

NOVEMBER 1967

FDA PAPERS

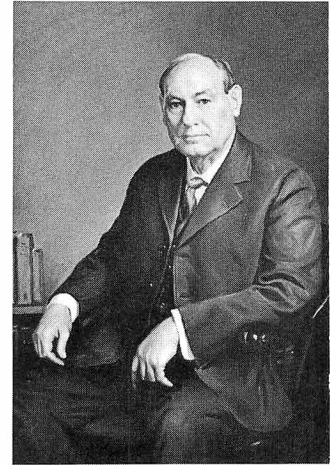
The Rx Label: Basis for All
PRESCRIBING INFORMATION

FDA Projections
A View of the Future

EMPLOYMENT PATTERNS
In the Drug Industry

**IN THE
WAKE OF DISASTER**





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

Harvey W. Wiley

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

Tradition influences a society to the degree that the past is respected by a significant number of individuals who bring their influence to bear on the mores and laws governing contemporary standards. Change occurs when tradition is no longer respected as viable in contemporary society and is relegated to remembrance of times gone by.

Something similar happens to tradition of organizations. "Don't tell me: 'That's the way we've always done it!'" is a modern cliché. Modern business and organization leadership must be skeptical of tradition. Past methods of operation — even the reason for being — must be scrutinized. Tradition must pass the test of viability in the contemporary atmosphere.

The tradition of law enforcement as the sole role of a regulatory agency is under scrutiny at FDA. Viewed as a role capable of growing in the present and in the future, law enforcement must be measured against the problems envisioned. The problems FDA foresees are consequences of a greatly expanding population and the corollary growth of food and drug industries. The measurement results in an appalling increase in regulatory personnel, and a fantastic — by current measure — expenditure of funds.

FDA wants to be viable, but not in terms of size. There must be a way of doing it better. So the Agency must ask (see page 27): "Doing *what* better?"

quotes

“We feel that our educational responsibility is as important as our enforcement responsibility if we are to succeed in protecting the public; hence, we are happy to work not only with pharmacies in the United States but also with all other groups interested in protecting the health and welfare of our consuming public.”

Paul A. Pumpian, Director, Office of Legislative and Governmental Services, to the Canadian Pharmaceutical Association, August 16, 1967.

“The relevance of animal toxicity data to man has been a subject of frequent discussion, and if there were any easy answers they would have been uncovered long since. It has been facetiously suggested that preclinical studies are far too important to do on animals. Therein lies our dilemma. We desperately need an accurate, up-to-date road map to guide us in our clinical evaluation of each new drug in man, and all we can get before we start out are maps of a couple of other countries which, in general, have the same topography. There are two obvious ways of reacting to this stressful situation. The first is to decide that since the maps are imperfect they should be improved. This means more thorough tests on more species at more dose levels, and gives us more precise information on not just one but several places we're not going. The opposite reaction is to become impatient with animal testing, reduce it to a minimum, and get into the clinical work as quickly as possible. Neither of these extremes is the answer. Animal tests can alert us to many, but not all, of the difficulties that will come up in the clinical trials. On the other hand, there is a point of diminishing returns in animal studies and we must never lose sight of the fact that they are not an end in themselves but merely one step in the evaluation of the safety of drugs in man.”

Bert J. Vos, M. D., Division of Toxicological Evaluation, Bureau of Science, to the Symposium on the Evaluation of New Drugs: The Challenge for Safety and Efficacy, of the Fall Meeting of the American Society for Pharmacology and Experimental Therapeutics, August 31, 1967.

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

James L. Goddard, M.D.
Commissioner of Food and Drugs

Gifford D. Hampshire / Editor

Sheldon Cohen / Art Director

Bob Barton / Asst. Art Director

Joan M. Galloway / Managing Editor

Frederick L. Townshend / Production Mgr.

PHOTOGRAPHY: John Crane, inside front cover, 10-15; George Tames, 4; Woleben/Photo, 19; Mark St. Gill-Black Star, 19-23; FDA, 24-26, 34; Michigan State Department of Agriculture, 35; Kent L. Woodman, upper left 24, upper right 26; Sheli Hershorn-Black Star, 28, 30.

FDA PAPERS, the official magazine of the Food and Drug Administration, is published monthly, except for combined July-August and December-January issues. Subscriptions may be ordered from the Superintendent of Documents, Government Printing Office, Washington, D. C. 20402, at \$5.50 a year (\$1.25 additional for foreign mailing).

Articles published in **FDA PAPERS** are in the public domain and text may be republished without permission. Use of funds for printing this publication approved by Director of the Bureau of the Budget August 15, 1966.

Employment Patterns in the Drug Industry—1966	A report by the Equal Employment Opportunity Commission.	4
The Rx Label: Basis for All Prescribing Information	What the package insert is and what it means to the physician.	10
In the Wake of Disaster	On-the-scene reports of the Fairbanks, Alaska flood and the Brownsville, Texas hurricane.	16
FDA Projections	New thinking by the Agency about its future.	27
Field Reports		31
State Actions		34
Seizures and Post Office Cases		36
Notices of Judgment		41

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

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

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

Advisors to the Editor*

H. Nelson Fitton, Department of Agriculture; Wayne Phillips, Department of Housing and Urban Development; Henry B. Montague, Post Office Department; Henry Scharer, Department of Commerce; Dr. John L. Buckley, Department of the Interior; Dr. Sam Kaim, Veterans Administration; Dr. Peter V. Siegel, Federal Aviation Agency; Dr. Spofford G. English, United States Atomic Energy Commission; Dr. Harve J. Carlson, National Science Foundation; Howard J. Lewis, National Academy of Sciences; Edward J. McVeigh, Public Health Service.

*The Food and Drug Administration is solely responsible for the contents of **FDA PAPERS**. The Advisors to the Editor are consultants on matters relating to the functions of the Federal Departments and Agencies listed.

minority group employment patterns in the drug industry

a report
by the Equal
Employment
Opportunity
Commission



Dr. James L. Goddard, Commissioner of Food and Drugs, and Clifford L. Alexander, Jr., Chairman, Equal Employment Opportunity Commission, invited executives of the drug industry to discuss minority employment patterns. They met in the Executive Office Building on October 6. Other Federal agencies participating were the Office of Federal Contract Compliance and the Veterans Administration.

Invitations were issued to those drug firms with one thousand or more employees.

*Statement by
James L. Goddard, M.D.
Commissioner of Food
and Drugs*

The Food and Drug Administration has a dual interest in joining with the Equal Employment Opportunity Commission to cosponsor the meeting.

First, it shares with all Federal agencies a responsibility to support and encourage, in every way possible, full compliance with the public laws and executive orders calling for positive steps to insure equal employment opportunity.

Second, it bears the major Federal responsibility of guaranteeing to consumers that the food, drugs, and cosmetics entering the marketplace do not violate standards established by public law.

There is no inconsistency in these two national goals. Employers can and must improve their hiring practices while maintaining the high quality of American goods. The President has urged that every agency of Government do what it can in this matter.

The FDA expects to play its proper role in support of both of these national mandates.

Before raising the subject with you, FDA reviewed its own personnel practices. We found that last year, 15.6 percent of our 4,700 employees were from minority groups. Their job stations ranged from unskilled work to administrative direction of our Bureau of Medicine. In our GS-12 through -18 jobs—in which you will find our top-ranking physicians, pharmacologists, microbiologists, and administrative personnel—3.4 percent were from minority groups. One step down—among the bench chemists, pharmacists, inspectors, budget officers, and other skilled white-collar personnel who fall within the GS-5 through -11 categories—12.9 percent were from minority groups.

We are proud of our record thus far. But we have no illusions about the need to do better. We have a long way to go to fulfill the commitments made by the President and the Congress for expanding

equal employment opportunities within Government. Our Agency has appointed a specific individual who is responsible for seeing how well we carry out our part of that job commitment. This person reports directly to me. My immediate Office is also kept abreast of all efforts in recruitment and career development in which equality of employment shall be considered. Each Bureau and Staff Office also has an individual responsible for making sure that the best efforts are made in his own area of work.

Each company here today has more than a thousand employees on its payroll. Together, you manufacture more than 70 percent of the drug products marketed in this country. To a great extent, you are determining the course of the drug industry. Your research investment, your investment in new facilities and equipment, and the increasingly important position you are assuming within the total health effort—all these factors present you with a unique opportunity for leadership in the employment area. It is to such industries as yours that we must look if this country is to provide meaningful jobs to all Americans.

In my visits around the country, stopping by many of your plants and talking with your people on the job, I have been impressed with the variety of occupations which—when brought together by your managements—constitute the drug industry. Pharmacists and chemists, clerks, accountants, physicists and electronics engineers, computer programmers, batch-mixers, storekeepers, physicians, machine operatives, printers—the range of jobs is impressive and is also indicative of opportunities for many of our fellow Americans who have been passed by.

Now we are all aware of the im-

portance of people to fill jobs at virtually every level today. Our recruiters frequently cross paths with yours. There may be differences among companies and among geographical areas. But as an industry, your personnel shortages run the gamut of skilled and unskilled positions. As you grow, this general problem will remain the same, although the specific jobs themselves may change. My colleagues here from other agencies have the statutory responsibility to see that equal employment opportunities are available to the greatest possible extent. They also represent agencies with whom you do business. The position of the FDA, however, is different. We have no statutory responsibilities in regard to employment opportunities. Nor do we purchase your products. But we do have a primary interest in making sure that the flow of pharmaceuticals from your production lines is constant and of the highest quality. In this, I believe I share with each of you an identical concern. Will a commitment to do more for equality of job opportunities present you with any new problem in your plant, in your sales offices, in your laboratories, or elsewhere? Then let's face it honestly together—today—and get on with our business of producing good drugs for the Nation.

FDA is prepared to share some of the stress. We want to be of assistance, particularly in bringing industry and Government together *before* misunderstandings arise. Our staff is ready to discuss with your people what some of your concerns may be. We are also prepared, along with the staff of the Equal Employment Opportunity Commission, to provide technical assistance and specific materials

when these are needed as well.

We are aware that new personnel practices may contribute an additional human error factor. We all know that in your business, error of any kind can affect lives. Perhaps by elevating our awareness of manpower problems we can, together, develop the kind of motivational and training techniques that will make your present and future employees more conscious of the vital role they play in safeguarding the Nation's health.

We pledge to each of you that the Food and Drug Administration is ready to be your partner in proving that your industry can contribute to the Nation's fight against discrimination even as it contributes to the fight against disease.

*Statement by
Clifford L. Alexander, Jr.
Chairman, Equal Employment
Opportunity Commission*

We at the Equal Employment Opportunity Commission welcome the association with the Food and Drug Administration—and with all Government agencies—to help us achieve the national goal of equal employment opportunity.

Our Commission's interagency associations follow President Johnson's call for a partnership among Federal agencies as well as with State and local governments to get the job done.

We want to talk to you today because our analysis of the employer reporting forms you filed with the Commission last year indicates that all Americans may well *not* be equal in seeking a job in your industry.

Your industry is by no means the only one whose employment data leads us to a similar conclusion. We have, for example, under-

taken a program to open up jobs for minority group members in the textile industry of North and South Carolina based on an analysis of their employer reporting forms which indicated substantial underutilization of Negro workers. We have plans to sit down with other industries whose employment data shows the far-too-common pattern of low utilization of minority groups and their concentration in lower level, low-paying jobs.

What do we plan to accomplish today?

First, we want to show each of you, who is undoubtedly aware of minority employment patterns in your own company, the picture for the industry as a whole. We do not believe it is a picture of which you will be proud.

Second, we want to describe the kind of effort that could help change that picture. We want to attempt to avoid, in both your interest and ours, the time-consuming complaint process which could well be the inevitable alternative to the kind of voluntary action we seek to initiate today.

Let us make no mistake about it: it is *action* we seek. No such action is possible without the commitment of top industry management. Your presence here today, I think, bespeaks that commitment. But commitment alone does not create action. And that is why we hope that follow-up programs we will discuss today will help you translate your commitment into action.

What is the kind of action we seek?

We in the field of equal employment opportunity often draw the distinction between "voluntary compliance" and "affirmative action." The latter is characterized by efforts to *promote* significant utilization of minority manpower

rather than simply to refrain from preventing it.

Very often when a company considers whether to undertake affirmative action it recoils on the basis that it is undemocratic . . . that it represents discrimination in reverse.

Equally often the company is hesitant because of fears that it would have to reduce its standards and jeopardize the product it is in business to produce. Let us be clear that we will not call on you for *indiscriminate* hiring; but we will call on you for truly *nondiscriminatory* hiring.

Let us be clear, too, that we do not advocate a slackening in your quality control to facilitate equal employment opportunity; but we will certainly call on you to recognize that a legitimate concern for quality control becomes a fetish when applied to the many jobs in your industry not directly concerned with critical points in the production process.

To achieve equal employment opportunity in your industry will mean elimination of certain practices whose effect, however unintentional, has been to exclude minority groups from meaningful positions in your work force. We will ask you to explore whether the scarcity of qualified job applicants you may perceive is truly a scarcity, or rather a reflection of your failure adequately to tap labor resources which do exist.

We will ask you to face honestly the fear that tapping these resources need result in lowered standards for hiring, upgrading and, indeed, output. To face it in light of our experience that it is far too often a groundless fear.

Returning to an earlier distinction, is what we seek your voluntary compliance with Title VII of

the Civil Rights Act of 1964, or is it affirmative action to increase the participation of minority workers in your industry? We can do no less than *demand* the former, because the figures you will see shortly suggest so strongly that compliance does not now exist. And we hope we can *expect* no less than the latter from you as an industry. Your shining record in promoting the Nation's physical health ought not to be tarnished by a disregard for symptoms in your own industry of the virtual cancer threatening the Nation's economic and social health.

The Office of Research and Reports of the Equal Employment Opportunity Commission has completed a study of employment opportunities for minority group workers in the drug industry.

Minority manpower patterns were reviewed in the context of the demand for pharmaceutical products and projections of labor requirements for this industry. Key elements of this context were, first, a recent history of rapid growth in output and favorable prospects for long-term demand. High levels of economic activity in the industry, past and present, can be associated with extensive new product introductions, improved health standards, and expanded health programs.

The second element of the context was the predominantly white-collar (approximately 60 percent of employees) character of the industry with future employment increases to be concentrated in white-collar jobs (officials and managers, professionals, technicians, salesworkers, and office and clerical workers).

Participation rates were calcu-

**TOTAL DRUG
INDUSTRY
EMPLOYMENT
1966**
5.3% Negro
2.1% Spanish
Surname

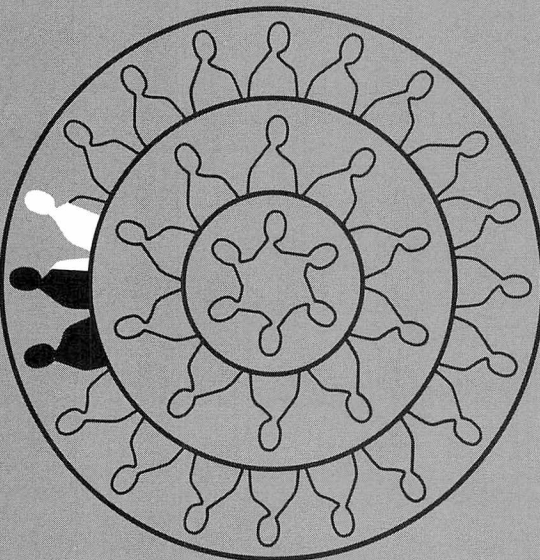


CHART ONE

the EEO-1 survey and 78.3 percent of total white-collar employment among reporting companies. The white- and blue-collar ratios were approximately the same as for the total industry, 60 percent and 40 percent, respectively.

CHART TWO: The Negro participation rate ranges from 0.6 percent to 25.4 percent. The overall percent for the sample is 4.4 percent. This can be compared with 5.3 percent for the total industry. The median percent for the sample is even lower, with half of the 30 companies falling below a 3.9 percent Negro participation rate.

lated for both Negroes and Americans of Spanish surname; however, Negroes are the largest minority group and are heavily concentrated in areas where the drug industry is located.

The principal finding of the 1966 employment survey is that Negroes constitute 5.3 percent of the 133,735 persons employed in the 398 establishments which filed EEO-1 reports on 1966 employment. Similarly, Americans of Spanish surname constitute 2.1 percent of total employees.

CHART ONE: In the nine Standard Metropolitan Statistical Areas, SMSA, which account for 62 percent of the 1966 drug industry employment reported on EEO-1, Negroes again represented 5.3 percent of total employees. The nine areas are: New York, Chicago, Newark, Philadelphia, Indianapolis, Los Angeles, Detroit, St. Louis, and Cincinnati. Negroes accounted for approximately 12.3 percent of the total population in 1960 in these nine areas. We know, for example, that there has been growth in the Negro population in these areas since 1960 and that the 1960 census itself undercounted the Negro population.

In order to delineate more pre-

cisely occupational patterns by racial groups, we selected a sample of 204 establishments representing 30 major drug companies. Each company had more than a thousand employees, and the total sample represented 75 percent of the employment of the drug industry in

Negroes hold only 1.8 percent of white-collar jobs reported by the 398 establishments under EEO-1 for 1966. In the special sample of 204 establishments, the underrepresentation of Negroes is even more marked. Negroes hold just 1.5 percent or 911 of the white-collar posi-

CHART TWO

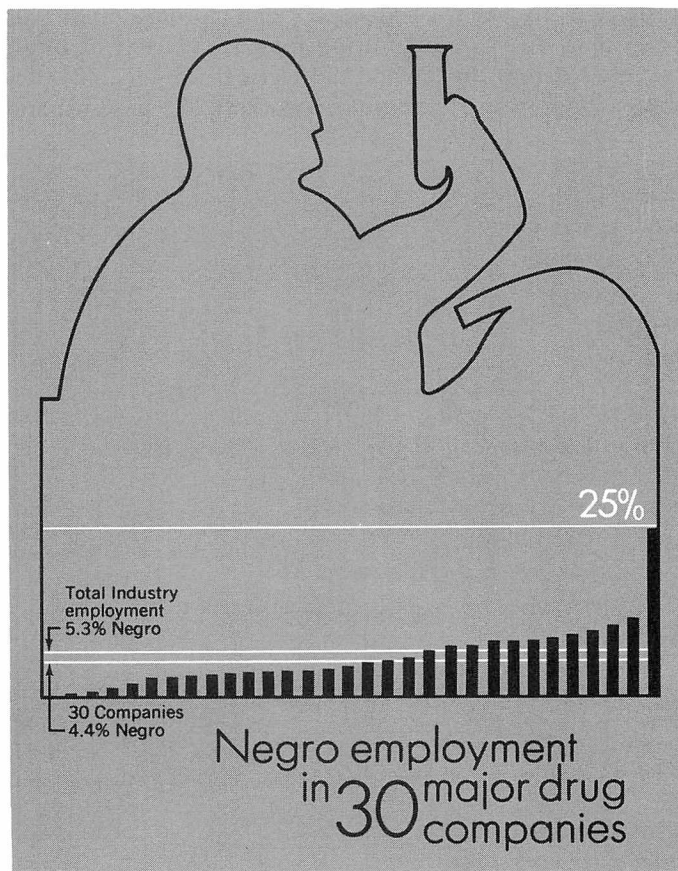


CHART THREE

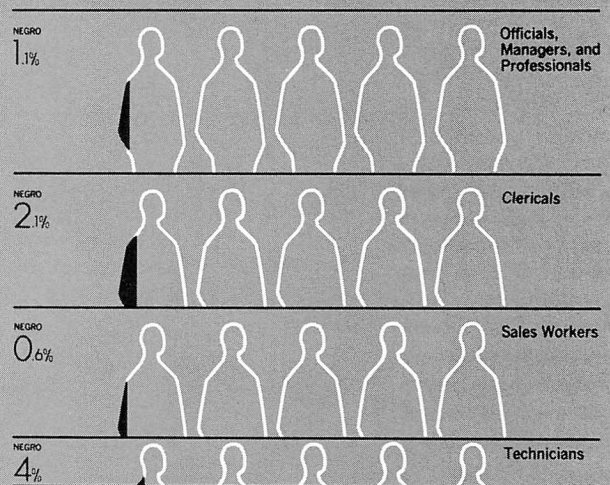
tions. The Negro white-collar utilization rate for the 30 major companies shown in Chart Two ranges from 0.4 percent to 5.2 percent with 15 of the companies ranked below 1.4 percent.

CHART THREE: Negro technicians hold only 4 percent of these jobs. Negro officials, managers, and professionals account for 1.1 percent of their category. In office and clerical positions, Negroes comprise only 2.1 percent of the 15,893 positions. Unlike the professional and technicians category, these jobs do not require advanced education and specialized training.

The smallest representation of Negroes in the white-collar work force was in sales positions (91 persons or 0.6 percent of all salesmen in these companies). It is interesting to note that there are not even enough Negro salesmen to cover the 9,000 Negro doctors and dentists in the United States, if Negro salesmen were restricted to such coverage.

Underutilization of Negroes in sales jobs contributes importantly

White
collar
employment
in 30
major drug
companies
1.5% Negro



to the pattern of low Negro penetration in white-collar jobs as a whole, since sales jobs are an important and growing segment of total white-collar employment in the industry (26 percent of all white-collar employment in 1966, up from 19 percent in 1960). Chart Three is scaled to show officials, managers, and professionals accounting for 35.3 percent of total; office and clerical workers 28.4 percent; salesworkers 26.3 percent; and

technicians 10 percent.

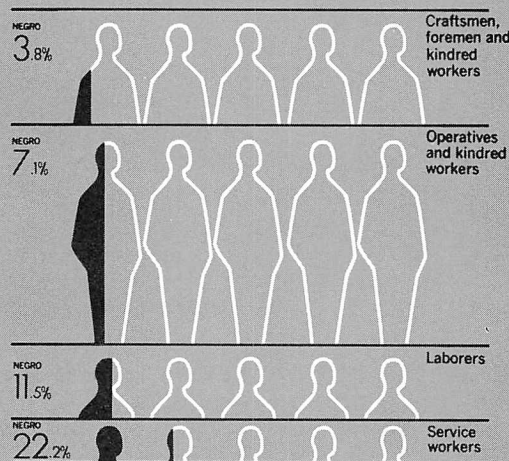
CHART FOUR: Negroes constitute 10.0 percent of blue-collar employees reported in the total EEO-1 survey as compared to the 8.6 percent of all blue-collar workers in the special sample. At least half of the Negro blue-collar workers are concentrated in the unskilled occupational categories (laborer and service workers) — this, despite the fact that the largest concentration of blue-collar jobs in the industry is at the semiskilled level (operative and kindred workers). Negroes held only 7.1 percent of the 19,114 operative jobs in 1966.

Many of the operative jobs are essentially the tending and operating of machinery and equipment. According to the 1965 edition of the *Dictionary of Occupational Titles* published by the U. S. Department of Labor, such jobs require little or no previous experience and indifferent scholastic records, with success important only in machine shop courses.

Craftsmen and foremen were the next largest group of blue-collar workers, accounting for about one-fourth of all blue-collar jobs. These jobs require more training and on-the-job experience. For some positions, apprenticeship pro-

CHART FOUR

Blue
collar
employment
in 30
major drug
companies
8.6% Negro



grams represent the best entry route. Negroes hold only 3.8 percent of the 9,996 craftsmen jobs. Chart Four is scaled to show the relative sizes of blue-collar categories, with operatives representing 47.4 percent of the total; craftsmen and foremen 24.8 percent; laborers 17.7 percent; and service workers 10 percent.

Thus, we find that past employment practices in the drug industry have led to a concentration of Negroes in blue-collar jobs. The chances were four in five that Negro employees in the drug industry would hold blue-collar positions as compared with the two in five for total employees. In an industry which is becoming more white-collar, operation of these past trends will tend to penalize Negro employees disproportionately.

Compounding the problem of low overall representation in both blue- and white-collar jobs is a pattern of the absence of Negroes from the generally higher-paid positions within each category.

CHART FIVE: The average blue-collar worker has a one-in-four chance of being a foreman, craftsman, or kindred worker; the Negro blue-collar worker has but one chance in ten.

Those Negroes in white-collar positions within the 30 major drug companies studied are distributed, significantly, more heavily among office, clerical, and technician positions than would be expected on the overall incidence of these positions in the white-collar category.

Chart Five also shows that while on the average a white-collar employee has about one chance in four of being a salesworker, a Negro white-collar employee has but one chance in ten. One in seven white-collar employees is an official or manager; for Negro

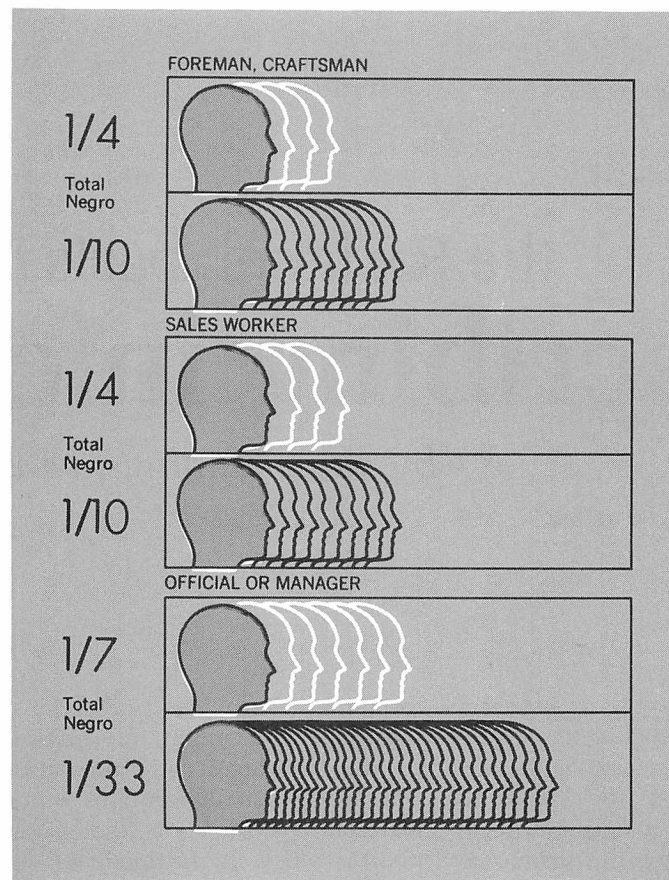


CHART FIVE

white-collar employees, only one in 33 is so employed.

EEOC's analysis of employment patterns in the drug industry raises several questions for further investigation. These relate to (1) differential participation rates for large and small companies and (2) the geographic location of plants. Apparently some of the smaller drug companies (250 up to 1,000 employees) utilize Negroes at a higher rate than some of the larger firms.

The 1967 Manpower Report of the President noted that many Negro workers—especially the younger ones—have more education than they need for the jobs they can get. Almost 35 percent of the nonwhite men in the labor force had 4 years of high school or more in 1965 and 7 percent had completed college, but only 17 percent were in white-collar positions. Among nonwhite women workers, the proportion with 4 years of high school education or more was 44 percent and 9

percent were college graduates. Yet only 26 percent were in white-collar positions.

In comparison, the figures for white workers show significantly larger proportions in white-collar occupations. Influences other than low educational attainment seem to be important in bringing about the inferior occupational structures of Negroes.

In the nine metropolitan areas where the drug industry employment is heaviest, from 24 percent up to 38 percent of Negroes had completed 4 years of high school or more in 1960. Since 1960 there has been a significant increase in the educational attainment of young nonwhite workers.

What are the implications for minority manpower? The longrun outlook for manpower needs in the drug industry is promising.

In the shortrun, on-the-job training and upgrading of minority workers already employed need to be emphasized.

the Rx label: basis for all prescribing information

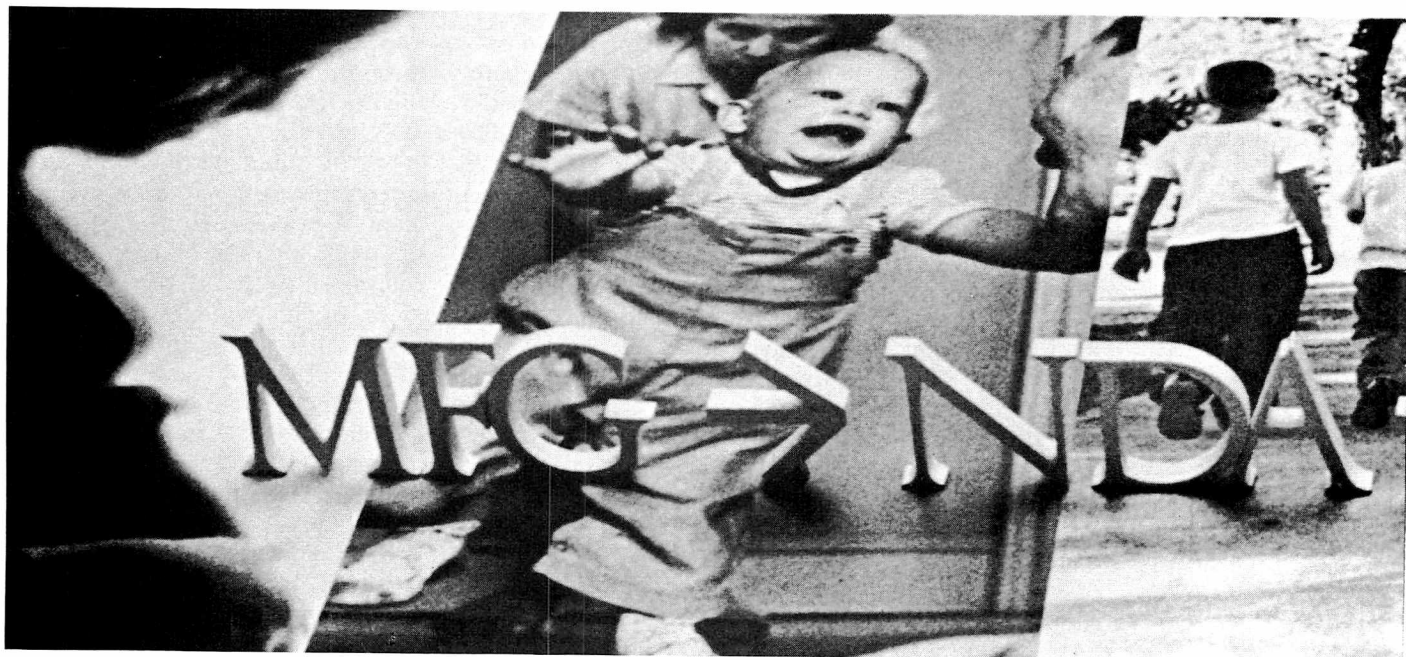
by John Jennings, M.D.

The basic purpose of prescription drug labeling is to provide the physician with adequate information for safe and effective use of a particular drug. The package insert, the prime example of labeling, is the document which is on or within most prescription drug packages, including trade containers and special purpose packages such as those used for promotional mailing. The package insert includes required in-

formation such as indications, warnings, and other information relating to the drug's safety and efficacy. It usually contains other material relating to the basic pharmacology in the mode of action and the conditions for which the drug is indicated.

The package insert is concerned with a drug. It is not intended to instruct the physician in the diagnosis of diseases, or in recognition of pathological conditions; nor is it

intended to replace the physician's basic medical education in pharmacology or drug therapy. In this limited sense the modern package insert represents the best source of established information available to the practicing physician regarding the conditions of use under which a drug is considered safe and effective. The conditions of use listed in the package insert are those for which the manufacturer of the drug has submitted data that



satisfy the criteria expressed in the Federal Food, Drug, and Cosmetic Act.

Although the package insert is the prime example of R_x labeling, this term, as defined by the Federal Food, Drug, and Cosmetic Act, includes all written, printed, or graphic material which accompanies the drug while it is in interstate commerce. Brochures, mailing pieces, catalogs, and similar material distributed by or on behalf of drug manufacturers that contain drug information are considered as promotional labeling. The material contained in the approved package insert serves as a basis for, and sets the limits of, this promotional labeling as well as journal advertising.

The package insert evolved out of a need to present the physician with data on a drug's usage and effects apart from advertising and promotional literature of the drug manufacturers. The Federal Food, Drug, and Cosmetic Act of 1938 requires that the labeling of drugs bear adequate directions for use; but no distinction was made between over-the-counter and prescription drugs. The Secretary of Agriculture, who then administered the Act, later exempted prescription drugs from the requirement. It was felt that physicians were experts in drug usage and did not

need labeling directions.

Because of the rapid increase in the number of new drugs after World War II, many physicians found it difficult to keep abreast of the field through traditional medical communications. Dissemination of drug information became a major function of pharmaceutical manufacturers. Often the physician obtained most of his information about a new drug through the manufacturer's advertising and promotion systems. He was not always made aware of the drug's side effects, dangers, or contraindications.

To remedy this situation, in 1961 the FDA promulgated a regulation that provided for a package insert to be on or within prescription drug packages. Known as the "Full Disclosure" regulation, it required that:

"Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is adver-

tised or represented. . . ."

The package insert originates as a part of the manufacturer's original New Drug Application. A draft of the insert based on data from animal testing and premarketing clinical trials is submitted with the NDA. The package insert, as finally approved, represents a distillation of these data establishing the drug's safety and efficacy.

According to the Federal Food, Drug, and Cosmetic Act, in order for an indication to be listed in the package insert it must be proved that the drug is safe and effective for this purpose. The proof must be in the form of adequate, well-controlled studies conducted by investigators with the training and experience to enable them to interpret such studies. This information is usually submitted to the Food and Drug Administration in a form similar to that of a medical journal article. The investigator outlines his objectives, selection of patients, safety and efficacy criteria, and the various parameters to be measured. Unlike a journal article, however, the FDA submission also contains the patients' work sheets. From these it is possible to reconstruct a study and to draw an independent and perhaps different interpretation. As a rule, studies by more than one well-qualified investigator are required to sub-



NAME DESCRIPTION ACTIONS INDICATIONS CONTRAINDICATIONS PRECAUTIONS DOSAGE & ADMINISTRATION

stantiate efficacy of a drug for a particular indication.

FDA Regulations require that adverse effects believed caused by the drug be reported to the Food and Drug Administration and to other investigators working with the drug during the premarketing testing. By the time the drug is ready for approval there has been built up a body of knowledge concerning adverse effects based both on animal testing and clinical trials. This information is included in the package insert under such headings as "Contraindications, Warnings, Precautions, and Adverse Reactions."

Because new therapeutic entities are rarely tested on large numbers of pregnant women, it is difficult to establish unequivocally the safety of the drug for use during pregnancy. In order to gather as much information as possible, and provide maximum safety, the FDA has established guidelines for animal reproduction studies. Divided into three segments, the guidelines provide for a general study of fertility and reproductive performance, teratologic and embryopathic potential; and perinatal and postnatal effects. Data derived from these studies are considered in labeling although it is recognized

that animal experience cannot be used to predict with certainty human safety.

If the animal data contain nothing significantly unfavorable, the package insert will usually bear a statement that the safety of the drug in pregnancy has not been established and its use in pregnancy is not recommended. The manufacturer is given the opportunity to cite acceptable animal data containing no adverse information. He may also include any information on use of the drug in pregnant women obtained during premarketing trials.

If the animal data contain unfavorable results and there is no human experience to contradict this, or if there is insufficient information on human use to make a safety determination, the drug is usually labeled as contraindicated in pregnancy.

Another area that receives close attention is the pediatric dosage schedule. Such a schedule is not permitted under the package insert "Dosage and administration" heading unless enough data have been presented to show that the schedule would provide for safe and effective use of the drug in the various age ranges listed.

When there is evidence that a drug might cause severe adverse effects in children, it is usually contraindicated in the pediatric age group. Most recently labeled drugs carry a package insert statement that the drug is not recommended for use in children unless adequate studies have been submitted to support such use.

The typical package insert often consists of a single sheet of paper placed in the drug carton or attached to the label of the immediate container. Its contents are usually arranged under an order of headings which is recommended by the Food and Drug Administration. The order is: Name of Drug, Description, Actions, Indications, Contraindications, Warnings, Precautions, Adverse Reactions, Dosage and Administration, and References.

Name: This must include the established or "generic" name of the active components. The structural or graphic formula may be given along with the chemical name. Forms other than oral must list inert ingredients as well.

Description: This includes a physical-chemical description of the active components, and of the dosage form when it has some bearing

DESCRIPTION INDICATIONS WARNINGS ADVERSE REACTIONS ADMINISTRATION

on the product's effectiveness. Data given may include such items as melting point, solubility, and stability.

Actions: This includes the pharmacologic effects in animals and man, including absorption, metabolism, excretion, etc. Such basic animal data as acute LD₅₀ may be included here.

Indications: The indications for a drug's use are now listed as specifically as possible. If the drug is not definitive treatment but rather an adjunct, a statement to this effect may be required.

Contraindications: This includes absolute contraindications and perhaps strong relative contraindications. If the drug is contraindicated in pregnancy, this information is given here.

Warnings: This includes extraordinary hazards, dangers of treatment, special conditions, and sometimes important precautions. If there is any question of safety in pregnancy, the information is presented here under the heading "USE IN PREGNANCY."

Precautions: This includes cautions to be observed in the use and administration of the drug under routine and special conditions.

Adverse Reactions: This includes

all known adverse reactions, including side effects, and those adverse reactions in which a causal relation is strongly probable. Drugs that have essentially the same indications and that pharmacologically belong to a "class," such as the thiazides, steroids, and phenothiazines, as a rule carry the "class" adverse reactions unless there is good evidence that they should be exempt.

Dosage and Administration: Here are listed the recommended dosage, routes, frequency and duration of administration for various indications and age groups. If common labeling is used for more than one dosage form or mode of administration (for example, for intramuscular and intravenous), any difference in preparation and administration is to be clearly stated.

The Food and Drug Administration's concern with the package insert does not end with the approval of the New Drug Application. Each time a manufacturer makes a major change in the production of a drug or a change in mode of the drug's presentation to the medical community, he must submit a supplemental application to the original NDA. For example, after FDA's approval, a manufacturer often continues investigational research for

indications other than those approved in the package insert. When the manufacturer feels he has sufficient data to support new claims, he submits it as a Supplemental New Drug Application. This material is subjected to the same scrutiny as the original NDA; it requires "adequate well-controlled studies" for approval of efficacy. If the data meet FDA criteria, the supplemental application is approved, then the package insert is revised.

The Food and Drug Administration may also require labeling changes based on adverse information received about a new drug. These changes may add contraindications, warnings, precautions, or adverse reactions to the package insert, or may restrict the drug's use.

When a drug is first marketed, it is often accompanied by a promotional campaign that results in its widespread use by the medical community. This may uncover adverse effects that were not discovered in the premarketing clinical trials because of the relatively narrow range of patients tested. A serious adverse reaction that occurred in one patient in 1,000 might not be picked up in premarketing trials unless there

were perhaps 10,000 patients tested. In addition, patients in good clinical trials are carefully selected and usually receive only the drug being tested. After marketing the patients may not be as carefully screened; they may take several additional drugs at the same time which could result in drug interactions.

Information on adverse reactions reaches the Food and Drug Administration through several channels, the most important of which is from the drug manufacturers themselves. Manufacturers are required by FDA regulations to file quarterly reports on the drug for the first year it is marketed, semiannual reports the second year, and annual reports thereafter. These documents contain all adverse experiences the company is aware of, summaries of additional animal and clinical trials, and any other new information related to the safety and the efficacy of the drug.

In addition to its own work, the company is required to submit data on the drug's use published in medical journals. All such papers, at least in summary, must be sub-

mitted—not just those resulting from studies sponsored by the manufacturer. Distribution figures and samples of the package insert in current use are also submitted with periodic reports. Specimens of promotional labeling and advertising are sent to FDA as soon as they are placed into use.

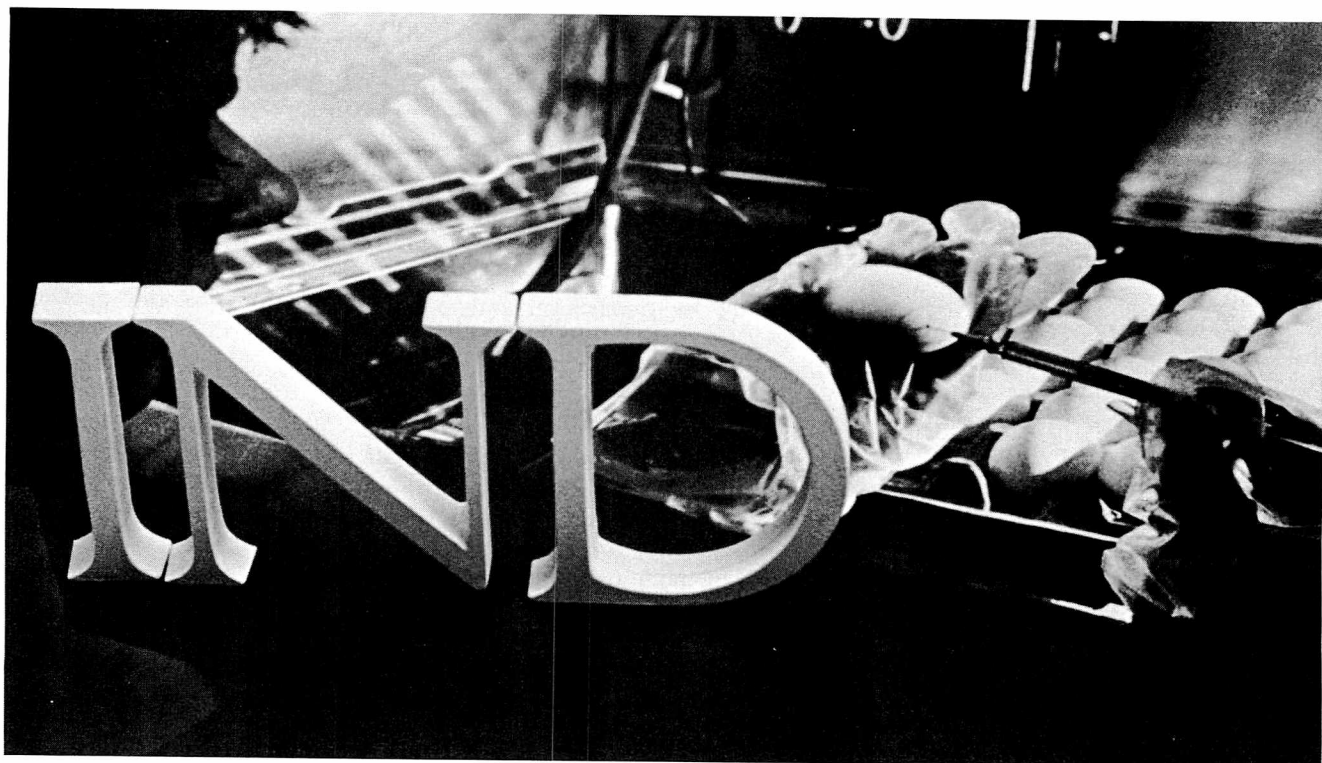
Additional information on adverse reactions comes from the FDA Hospital Reporting System, a network of 84 hospitals across the country under contract to report on adverse effects of drugs. In addition, doctors and patients frequently report reactions and adverse effects directly to the Food and Drug Administration. Regular bi-yearly inspection of manufacturing plants, which includes examination of the firm's records, occasionally turns up adverse reaction reports that have not reached the FDA for one reason or another.

Not all labeling changes relate to indications and precautionary statements. The Food and Drug Administration may require the manufacturer to place an expiration date in the labeling if stability tests or marketing experience show

that the drug declined in potency, or otherwise changed, over a certain period of time. Handling and storage warnings, especially in regard to exposure to light and temperature extremes, can also be added as a result of experience gained in marketing.

Package insert changes that include new indications, new dosage forms, or other modifications intended mainly to improve the drug's marketing are generally brought to the attention of the practicing physician by the firm's promotional efforts. However, when more serious changes are made in the cautionary sections of the package insert, the Food and Drug Administration usually requests the company to bring this information directly to the attention of physicians by means of a letter sent by first class mail in a distinctively marked envelope. These have become known as "Dear Doctor" letters.

It should be noted that the burden of proving the safety and effectiveness of a new drug—or of new uses of an already approved drug—rests on the manufacturer. It is the



manufacturer who chooses the indications to be investigated and determines the dosage level for which he will seek FDA approval. It is the duty of the Food and Drug Administration under the law to decide that proposed usages and levels are both safe and effective, based on the data submitted by the manufacturer.

Thus, when a new drug passes into the hands of the physician, the package insert information he receives is based on data the manufacturer has submitted to the Food and Drug Administration as his proof that the drug is safe and effective *in the uses for which the manufacturer wishes to market the drug*.

If the manufacturer wishes to claim new uses, he may do so by submitting a supplement to his effective New Drug Application.

If a doctor exercises a judgment to prescribe a drug outside the limits of the package insert, he should be aware that the scientific basis for doing so has not been established by data submitted by the manufacturer through the procedures required by law.

The investigational new drug procedures cover the use of a drug for conditions other than those in the approved labeling for which there is some rationale.

A physician's experimental use of an approved drug—without the submission of IND (claimed exemption for Investigational use of a New Drug)—does not violate *Federal* law since the drug has been lawfully shipped in interstate commerce for the approved uses.

The Food and Drug Administration, among others, is not satisfied that the package insert is the best possible method for reaching the physician with information on a drug's safety and effectiveness. The latest approved package insert is not always readily available to the physician, and some inserts contain information that, while factual, is purely promotional.

The future of the package insert is a subject of serious discussion throughout the medical community. Within FDA we believe the basic purposes of the package insert might be divided into three categories:

1. Adequate information to the physician for safe and effective use of the drug.
2. Education of the physician regarding a specific drug.
3. Factual basis and limitations for promotion of the drug to the medical profession.

The first purpose is required by the law and regulations and is, of course, the most important. The second purpose is probably desirable. The third purpose often involves the Food and Drug Administration in a regulatory sense.

Much thought has recently been given to revision of the package insert in order that it might fulfill its primary function, while allowing and perhaps encouraging the second function, and permitting and regulating the third.

Since there are no regulations strictly setting forth the format and the content of the package insert, it is not surprising that they vary widely. Because the Food and Drug Administration has been able to establish requirements for "full disclosure," a certain degree of uniformity has been achieved. However, much more could be accomplished in this direction.

One approach would be to establish an extremely simple format to fulfill the first function, and an expanded version which would cover the other two functions. The simplified or "summary package insert" would follow a standard format, give concise directions for use, and satisfy the "full disclosure" requirements. This concise insert would contain nothing smacking of promotion and could provide the basis for a drug compendium entry. Such a compendium would probably render unnecessary the requirement that a package insert accompany every package of the



John J. Jennings, M.D., is Acting Associate Director for Drug Surveillance, Bureau of Medicine.

drug, and at the same time make this information more readily available to the practicing physician.

The expanded version of the package insert, or final approved labeling, would also be subject to FDA approval and would be available to the physician through the usual channels—direct mailing, distribution by detail men, etc.—or available on request from the manufacturer. In some instances this expanded version might simply be the short version followed by the additional material such as pharmacology, both animal and human, clinical experience, and other material that could be approved. This version of the package insert would serve to increase the physician's knowledge about a particular drug, and to direct his attention to further sources of information. This final approved labeling would be of extreme importance to the Food and Drug Administration, because it would continue to serve as the basis for, and define the limits of, all promotional labeling and journal advertising as does the present package insert.

FDA has been discussing these possibilities for the future of final approved labeling with the drug industry and with the medical profession. It has been a long discussion, but it will continue until the proper means are found to provide physicians with the prescribing information they require to practice good drug therapy.

in the wake

Fairbanks Flood If they had it to do over, Fairbanks drugstore operator R. M. Fenton and milk distributor Art Sexauer would put everything much higher. Like 35,000 other residents of the 49th State's second largest community, together with another 9,000 at adjacent Fort Wainwright, neither man thought the Chena River would flood Fairbanks.

There had not been a summer flood in the 22 years since the Moose Creek dike was constructed to keep the Tanana River out of the Chena River upstream.

But after a wet July, 6 inches of rain fell in the 6 days preceding the flood night of August 14. This was nearly half the average annual precipitation in the semiarid Tanana Valley. The water began to sluice down the already saturated hills to the north.

During the night all Fairbanks became the channel of the meandering Chena, which reached a crest of 18.82 feet at 10 a.m. Tuesday, and was not back within its channel until the following Monday.

With depths ranging from a few to 9 feet in some areas, flat-bottomed riverboats churned through 8-knot currents, dodging everything from floating debris to parking meters in a massive evacuation. Military and private helicopters and trucks assisted.

The totality of the inundation of the Tanana Valley and the disruption of communications and transportation posed unique challenges—and none more immediate than assuring there would be enough safe food and water, medical care, and shelter for the evacuees.

From the State capital at remote Juneau, Health and Welfare Commissioner Wallace J. Chapman, M.D., flew into Fairbanks the day of the floodcrest. So did Deputy Commissioner Richard Lauber; Dr. Robert F. Cavitt, acting director of the Division of Public Health; and State sanitarians from other areas of Alaska.

Sanitary Engineers A. J. Alter and R. H. Britt, stationed at Juneau, had already asked the two Fairbanks radio stations on August 14 to advise residents to chlorinate small water supplies.

As the State's only environmental sanitarian for the northern half of Alaska, Wilbur P. Green's job normally is to inspect 650 food-handling facilities from the Canadian border to the Arctic Ocean.

Dr. Chapman assigned Green the responsibility of coordinating task forces to report the health of flood victims. Their duties ranged from chlorinating canned goods to trying to find rat poison to use

against the durable Arctic rodents that headed for higher grounds.

With the municipal sewerage plant submerged 4 feet and breaks in the system, Fairbanks was literally an open sewer. Toilet flushings would come back out of a manhole elsewhere. Although municipal power was retained, power to refrigerated lockers was flooded out. Meats and frozen goods had to be inspected, salvaged, or destroyed. Distribution and pickup systems had to be set up for food and good water, sanitary kits, and waste disposal.

In Seattle meanwhile, District Director Franklin D. Clark of the U. S. Food and Drug Administration had offered the full services of FDA to Commissioner Chapman. FDA Inspectors J. Kenneth Kinney and Lee C. Matthews from the Seattle District were recalled from other assignments and arrived in Fairbanks August 22. All the State, Federal, and local government technical personnel, including City Sanitarian Harry Masino, comprised a force of some 45, not counting nurses and welfare workers.

It was scarcely enough. Everything had to be done at once.

Undamaged foodstuffs were inventoried and transported to evacuee centers to meet the pressing need for food. As the stock of undamaged foodstuffs was depleted, Red Cross and Salvation Army workers were trained in sanitizing procedures and salvageable items were distributed for use. Food was flown in from Anchorage and there was never a shortage in the total area.

Floodwaters had forced the evacuation of patients from St. Joseph's Hospital, Fairbanks' only hospital, to the Fort Wainwright Hospital. Inspector Matthews visited the hospital August 24 and reported: "All drugs, injectables, and food submerged in floodwaters." The drugs went to a secret dump.

Matthews found an estimated \$200,000 loss at Market Basket, one of four Fairbanks supermarkets. He found a comparable loss at the Quality Meat distributing firm, but by the 28th "the coolers were cleaned and ready to go." He found an estimated \$200,000 loss also to non-Rx drugs and sundries at Co-Op Drug, one of five drugstore-pharmacies in the community.

Interviews with grocers, pharmacists, retailers, and wholesalers indicate that no hard feelings are harbored and that the degree of cooperation with State health and FDA men was high.

of disaster

At the large K & L Distributors' warehouse, Manager Dan Pekich described Inspector Kinney as "an old hand" and took a philosophical view of what transpired.

"Kinney explained that if it were only typhoid to worry about it would be a simple matter," said Pekich, "but there were unknowns to consider. What else could be in the water? So, to be on the safe side, he condemned everything that got flooded."

Sanitarian Green estimates that \$1.5 million in contaminated beverages, alcoholic and otherwise, was embargoed and destroyed. He estimated another \$1.5 million in contaminated foodstuffs was destroyed, and \$500,000 in drugs and cosmetics.

There was never any shortage of prescription drugs, according to R. M. Fenton, pharmacist and owner of the Northward Drug, although there was a distribution problem for several days.

From Nenana to Fairbanks the latest damage reckoning includes \$29.1 million in structural damage to private homes and businesses; \$50 million in personal belongings, furnishings, and store inventories; \$9 million for emergency repairs of utilities, streets, schools, and other work in the public sector being handled by the Army Corps of Engineers under direction of the Federal Office of Emergency Planning; \$2 million to the Alaska Railroad; and up to \$15 million for repairs at Fort Wainwright.

An unusual Indian summer has given Fairbanksans more time to pump out, dry out, and winterize before the freezeup and the onset of 40-below-zero-type weather. Toward the end of September there had been only mild frosts. This meant that Jack Frost would be less apt to catch up with the gradually lowering water table, ranging from 4 to 14 feet at midmonth. An early freezeup would mean more frost-heaving of the saturated earth with resultant damage to streets, foundations, and water, steam, and sewer lines; not to mention private septic tanks and cesspools in the subdivisions not served by municipal utilities.

A high water table would also call for a critical reckoning of the amount of cubic feet per second of water stored in the hills as snow versus the capacity of the Chena River channel next May.

But Alaskans are as optimistic as they are resourceful, and these characteristics applied as well to the State's sanitarians and the engineers and advisors who put together the teamwork to get a job done under a difficult situation. The FDA Inspectors added

needed ingredients to this successful operation—experience with similar emergencies and confidence in proper procedures for handling foods, and particularly drugs.—*David B. Galloway*

Texas Hurricane

A billion dollar hurricane, followed by one of the greatest floods on record for the Rio Grande, demanded and got a remarkable meshing of local, State, and Federal health task forces in south Texas in late September.

This finely attuned teamwork was in operation before hurricane-force winds died down.

Hurricane Beulah, now classified by the U.S. Weather Bureau as the third largest hurricane on record, slammed into the Lower Texas Gulf Coast in the early morning hours, Wednesday, September 20, leaving devastation in her wake and rainfall up to 20 inches in some parts of south Texas.

Packing winds of up to 145 miles an hour, Beulah ripped off roofs, smashed windows, destroyed homes and school buildings, took down power and telephone lines, and uprooted trees.

She left thousands homeless and isolated in a 43,000-square-mile area, as communication lines were felled and highways were closed by flooding.

Within 3 days after Beulah's erratic passage, the Lower Rio Grande Valley of Texas was faced with a new threat—the flooding Rio Grande.

Two days after the hurricane, cities and communities along this rich agricultural delta were asked by the International Boundary and Water Commission to close storm sewer gates to the floodway system. The IBWC, which administers and operates the floodway system, also asked the cities to end sanitary sewer effluent discharges into the floodways. This created rainfall runoff and sewer discharge disposition problems.

The Lower Rio Grande Valley, hardest hit by Beulah and in the path of the rampant Rio Grande, has a population of about 400,000.

Because of severe flooding experienced by adjacent Mexican communities, the international border was opened to allow free entry to Mexican refugees. Thousands were evacuated from their homes on both sides of the border and housed in school, church, and public buildings.

Power and water supply failure was of immediate concern. One of the largest valley cities, Brownsville,

was without power in some parts of the city 7 days after the hurricane. All cities and towns in the hurricane-struck area had power failures lasting from a few hours to several days.

Health agencies were confronted with a monumental chore. Cut off from new food supplies to replace that damaged by Beulah, residents were warned by local, State, and Federal health officials to take precautions with food, water, and drugs.

On Thursday, September 21, when hurricane winds were still in force, services of two microbiologists with the Dallas District Office of the Food and Drug Administration were offered to the Texas Department of Health. Additional FDA Inspectors were dispatched to the disaster area.

James B. Hyndman, supervisory microbiologist with the Dallas office, and microbiologist Charles Roderick were already on the scene. In Brownsville on another assignment, the two men stayed in the city when the hurricane alert was issued. They weathered the storm along with Brownsville's 55,000 population.

Within 12 hours after the disaster, inspectors from both the FDA and the State division of food and drugs were on the job. Hyndman coordinated initial activities.

Working with city and county sanitarians, the State and Federal Inspectors fanned out over the hurricane- and flood-ravaged area, checking wholesale and retail establishments to block flow of contaminated food and drugs to the public.

Operating out of the Brownsville Resident Office, teams of State and Federal food and drug inspectors concentrated on the immediate area of Brownsville, and the coastal town of Port Isabel.

Destruction or embargo of contaminated food and drugs got priority. Since 65 percent of breaded shrimp consumed in the United States is processed in the valley area, inspection teams had no small task. Invaluable assistance in communicating with the large Mexican-American population was rendered by registered Sanitarian Steve Tollos of Brownsville.

All water brought by Beulah was considered contaminated.

Initial efforts were aimed at collecting and destroying meats, poultry, and other foods contaminated by hurricane elements. Later efforts were in the area of collecting water samples from all food processing and ice plants, to insure that hurricane winds had not shaken pipes loose, causing them to become defective.

On Sunday, September 24, Boland B. Shepard, supervisory inspector of the Dallas FDA District Office, arrived on the scene and assumed coordination of activities. Teams consisting of State and

Federal food and drug inspectors were posted at McAllen, upstream from Brownsville some 60 miles, and other cities in a three-county area.

Brownsville City Sanitarian J. Benson Cooper looks upon the cooperative efforts among the different governmental agencies in time of emergency as a "natural thing."

"America is made up like that—we help one another," commented Cooper. He said in the first few days after Beulah in Brownsville, "We got lots done. We depended on the State and Federal Inspectors to find and identify the contaminated food, then we ordered it destroyed." Cooper said some 2 tons of food were burned or buried in Brownsville soon after the disaster, with most wholesale and retail concerns cooperating.

The State put an embargo on other food and drug supplies. Destruction of the damaged products was another problem. Muddy routes to municipal dump sites made the supervised hauling time consuming.

In some cases, food and drug inspectors were forced to stand or request guard on goods earmarked for disposal, to keep scavengers away. National Guardsmen stood guard on embargoed drug supplies. Persons on both sides of the international border traveled the alleys looking for food.

The goal of local, State, and Federal health officials in this disaster was to protect not only the consumer but also the manufacturer. Some firms readily stockpiled damaged goods, holding them for insurance adjustment.

Approximately \$4 million of frozen foods is being held voluntarily in one plant, pending segregation and bacteriological analysis. City and county sanitarians carried out inspection of restaurants and smaller retail firms.

Cleanup problems were monumental. Health officials, businessmen, and citizens faced weeks—perhaps months—of dirty, backbreaking work to sort out the filthy from the salvageable.

Damaged foods, drugs, and cosmetics in the flood's wake totaled approximately \$3,011,750 by October 18, reported Dallas District. An additional \$135,700 worth of animal feeds were damaged. Included in those figures are goods destroyed: foods, \$200,228; drugs, \$19,242; cosmetics, \$6,400; and feeds, \$21,360. The rest of the products were salvaged, embargoed by State or local officials, or held voluntarily by the owners for segregation. In Port Isabel, the complete stocks of one drugstore and several groceries were destroyed.

Dr. John Copenhagen, director of health departments in Cameron and Hidalgo Counties, both hard hit by hurricane and floods, summed it up: "We have more than we can get done on our own. Cooperative efforts of public health officials work awfully well." —*Betty M. Cardwell*





**winds
and
water
rip and soak
a third
of Texas**

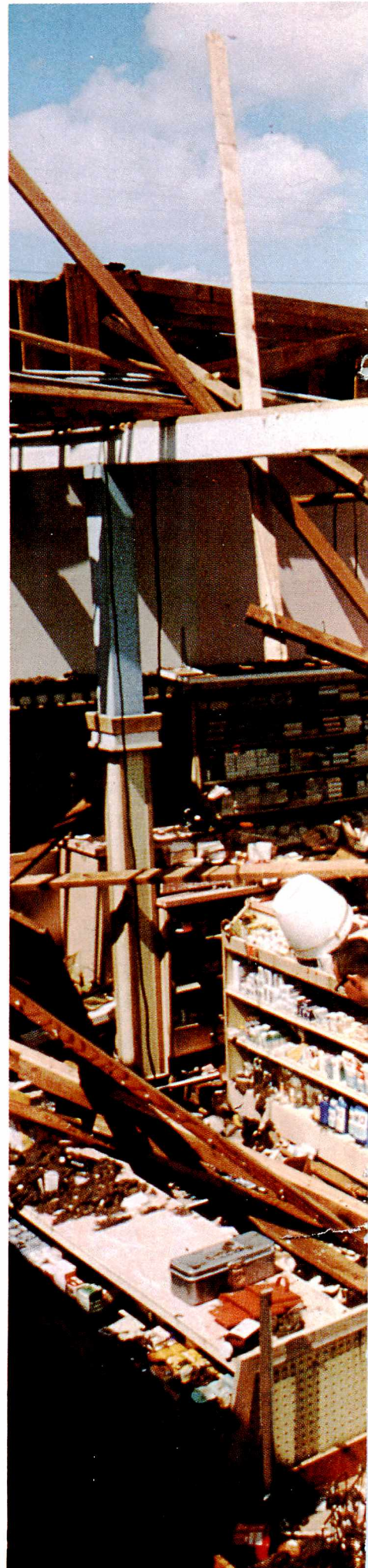
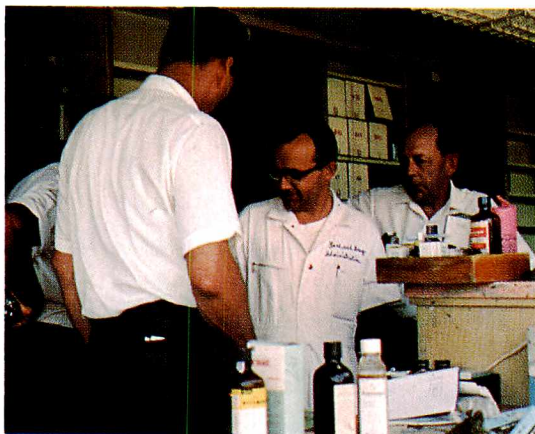
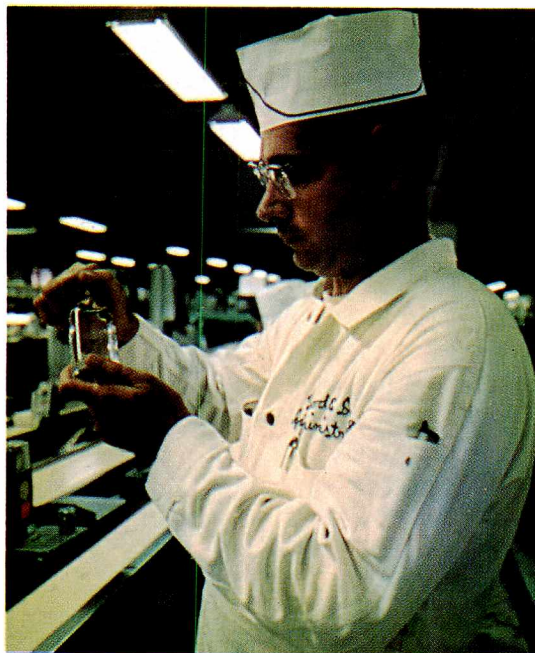




Sons of Port Isabel grocery store owner (far left above) help an employee gather contaminated food to be taken to the dump. The store lost its roof in the storm, which dealt its hardest blow to Port Isabel. "CONTAMINATED CANNOT BE SOLD UNDER ORDER OF THE DEPARTMENT OF SANITATION" (left above). FDA Inspector Raymond Moore (center) helps examine spoiled meat in a Brownsville grocery store; takes an inventory of the meat with Brownsville Sanitarian Steve Tullos (left below); and checks damage to the stocks (above). Brownsville FDA Resident Inspector John Hauser surveys damage to Port Isabel grocery store shown on previous page (above right). Thrown on the street by another Port Isabel store owner, this spoiled meat (right below) is infested by flies and maggots. Several days passed before health officials reached the area and told the owner to treat the meat with lime and bury it in the city dump. Such improper disposal of meat was attributed to ignorance rather than carelessness.



Shrimp boats were blown out of the Brownsville port (above) by the storm; stocks on the boats could not be salvaged. An FDA Inspector inventories water-damaged prescription drugs in a Brownsville drugstore (right top). FDA Bacteriologist (right middle) helps local health authorities by taking a water sample at a breaded shrimp plant. He took water samples at all seafood plants in the area and sent them to the Cameron County Health Department for analysis. Inspector surveys drug-store damage (right bottom).





Picking his way through debris at a Port Isabel drugstore, Inspector Hauser is followed by Food and Drug Inspector Lenwood Scholtz of the Texas State Department of Health (left). National Guardsmen (above top) keep a 24-hour watch on dangerous drugs at the demolished store until they can be destroyed. The guards were kept on duty for several days until workmen could be found to clear out enough wreckage so that health officials could reach and survey the prescription drug stocks. Garbage trucks haul foodstuffs to the Brownsville city dump (above bottom). Some 2 tons of food were burned or buried in the area soon after the disaster.



**an
Alaskan
community
rises
from an
open sewer**





Fairbanks residents are evacuated from flood dangers (far left). Others were taken out by helicopters and boats. FDA Inspector J. Kenneth Kinney examines drugs being removed from the Fairbanks Clinic (left). Bulldozer plows under contaminated drugs and foods at Fairbanks city dump (above). Due to the danger of looting and scavenging at the municipal dump, FDA helped set up a secret dump near an old gold mining town to bury beverages, dangerous drugs, and narcotics. American Red Cross workers decontaminate some of 40,000 pounds of canned food donated by a local grocery to feed evacuees housed in a school (right above). Seattle District Director Franklin D. Clark (center) dispatches FDA Inspectors Kinney (left) and Lee C. Matthews (right) to Alaska to help local health authorities in the immense cleanup task. Four feet of water in the 4th Avenue Pharmacy ruined the inventory of drugs and cosmetics. Two weeks after the flood the pharmacy's basement was still under water.





Drugs and cosmetics left unguarded outside flood-ravaged businesses were a problem for Inspector Kinney and local police officers (above). Chena River floods Fairbanks (right above). Parenteral drug stocks are removed from St. Joseph's Hospital basement (right middle); linen dries in the hospital's back yard, which faces the now quiet Chena (right below).



FDA projections a view of the future

by Edward Tuerk

When an agency takes on new leadership, it is always appropriate to outline some of the new thinking; to indicate to the FDA constituency some of the ways the Agency's operations are being viewed as a service contributing to society.

Any such discussion today must take as its point of departure the changes in overall Federal Government planning which is based on the Planning-Programming-Budgeting-System. Officially, this is the second year of P-P-B-S in the civilian departments.

The P-P-B-System requires that a governmental agency must conceive of itself as being mission-oriented; as having a job to do in some overall system in which the agency functions.

Thus, the Food and Drug Administration has been required—both in terms of its change in administration and in terms of the overall governmental system—to ask: “What kind of business is FDA in?”

Different answers are possible. For example, if the Food and Drug Administration is primarily in the business of regulation or law enforcement, there is one series of answers.

If FDA's mission is defined differently, the answers are different.

During the past year we have said that FDA is in the business of providing consumer protection; that law enforcement is merely one of the possible approaches to maximizing consumer benefit or minimizing consumer risk.

In addition to defining the Agency's mission and objectives, P-P-B-S requires that we examine the various alternatives to accomplish the objectives.

If we say that FDA is a consumer-protection agency, and that the law is only one tool readily available, this broadens the range of inquiry into alternative FDA programs. What will it do? What should it do? What must it do? Take drugs, for example. Considerations of benefits and risks lead to the question: “What, in fact, are the consumer risks or consumer benefits with respect to drugs?”

One major risk is the fact that the drug for a patient's disease or condition may not be available. It may not be available when it should be available, or

when it could be available. So, we ask: “What is the role of the Food and Drug Administration with respect to drug availability?”

If the concern of the Agency is to be the shortening of total time it takes to get valuable drugs on the market, rather than wholly with the NDA review time, this approach requires a change in some of the ways the Agency operates.

We estimate that significant therapeutic entities coming on the market have been in research, development, testing, and evaluation for 7 years or so. This 7-year time period then becomes the significant criterion, and the 180-day time period that is spelled in the law for NDA review loses some of its importance.

If the total time is to be FDA's concern, and if concentrating on the NDA review does not contribute significantly to making drugs available faster, what does this mean for the Agency?

It suggests that the Food and Drug Administration must relate more specifically to drug studies as they are designed in the early phases of drug testing. It suggests that the Food and Drug Administration must, in the future, involve itself more with industry in coming to agreement on the validity of protocols and the statistical tests of significance. In sum, FDA must be concerned with the totality of research project design and implementation.

This greater degree of involvement in the early stages should mean that when the NDA is submitted the reviewer already knows that research has been done and how valid it is. The review of the NDA itself then can be more routinized.

However, if, because of time delays, the Food and Drug Administration is to concern itself with the lack of available significant therapeutic entities for significant diseases, we also must determine if there are other factors which may contribute to non-availability of drugs. This inquiry could lead to the question: “Are there drugs of promise where research has been stopped because of economic considerations?”

At this point we are merely saying that we are



Food & Drugs
Administration

FDA is in the business of providing consumer protection; law enforcement is merely one of the possible approaches

attempting, in a systematic way, to look at all the problems of drug availability. This requires us to pinpoint those conditions contributory to the non-existence of products, and then to ask: "What is FDA's role?"

Another risk the consumer faces is that he may not respond to the drug that is available. At issue here, in part, is the question of therapeutic equivalency of generically or chemically equivalent drugs.

If one of the problems of drugs is that products may not be effective for the purpose for which they are labeled and advertised, although still meeting current compendia assay standards, then it becomes FDA's responsibility to reduce this consumer risk.

We envision the Agency's role in this area to include the development of protocols to test the therapeutic efficacy or physiologic availability of drugs with the same public name, and to sponsor clinical trials. To the extent that the same public-name drugs do have the same efficacy, this information should be publicized. To the extent that they do not, then action should be initiated to remove the offending drug from the market, or to improve the conditions of its manufacture to the point where efficacy can be assured.

Another consumer risk or hazard associated with drugs is the problem of drug safety. Assuming that the fundamental safety of a drug has been demonstrated in the review process, this becomes the problem of safety of marketed drugs.

A variety of things can happen in drug manufacture in terms of contamination, potency variations, and mislabeling. Again, FDA must ask: "What is the relationship of its current programs to drug safety as such, and what changes may be indicated?"

First of all, there are the Good Manufacturing Practice Regulations. In essence, these regulations state a series of conditions which, if in existence in manufacturing, reduce to a minimum the probability of nondetected error. When the Food and Drug Administration inspects a drug manufacturing operation, we are attempting to identify those conditions which create the potential for error. This ties

the FDA inspection program into the manufacturer's quality assurance program. The inspections identify the conditions which create probabilities of something eventually being wrong with the product.

If drug inspections, in relationship to GMP, are primarily an attempt to improve quality control, the findings therefore must be communicated to the manufacturer. This is different than looking at GMP primarily in an attempt to find actionable violations.

If FDA were wholly a regulatory agency concerned with detecting violations, then there would be no need to communicate findings to industry other than through legal processes. But, once we say the Agency mission is to minimize a risk or maximize a benefit, then the role changes. And, once the role changes, the operations must change.

FDA operations are changing to emphasize communication to industry of inspectional findings which, to the extent management is responsive, tend to correct the poor practices observed. Nonresponsiveness on the part of management, however, will still occasion the invoking of legal sanctions.

The redefinition of the Agency role has also modified the approach to product sampling. The St. Louis National Center for Drug Analysis, when it becomes fully operational, will permit continuous monitoring for quality of drugs in the marketplace at a point close to the consumer.

It is acknowledged that sampling at the retail level will primarily cover the products of the larger manufacturers. FDA must, of course, also concern itself with the products of the smaller manufacturers. There is being established a concept of manufacturer surveillance to be implemented through the FDA District Offices. The Districts will maintain surveillance over individual manufacturers, including those whose products may not be sampled through the national monitoring program.

However, the problem of drug safety is not entirely related to the product itself, or to its manufacture. We must consider physician-prescribing patterns, pharmacy practices, and patient use.

Good data are just not available on the diseases



and conditions caused by drugs. But limited studies suggest that there may be as many as one-half million annual hospital admissions because of reactions to drugs.

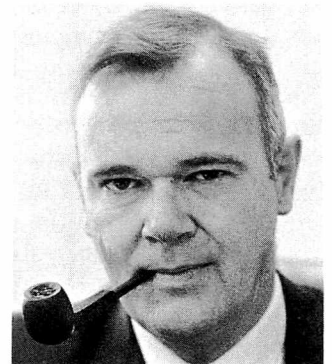
FDA must determine the factors which contribute to a problem of this magnitude. To the extent that physician prescribing contributes, the Food and Drug Administration should intensify its programs of information to physicians. In addition to providing authoritative full disclosure information on all drugs, FDA should perhaps communicate additional information on those drugs that seem to have the highest reaction potential. FDA should likewise determine if pharmacy error plays a major role in drug safety, and develop programs accordingly.

These, then, are some of the concepts which indicate the kind of movement that takes place within an agency when it defines its mission somewhat differently than it may have in the past. Concepts, however, do not constitute plans. The development of concrete plans takes time. The existing commitments, values, and attitudes of an ongoing and viable organization change slowly. But ideas must precede action.

Although the examples listed here relate primarily to drugs, considerations of consumer risk and consumer benefit are likewise influencing program direction in the areas of food, devices, cosmetics, and hazardous substances.

FDA projections for the future suggest increasing concern with the quality of the research used to support petitions and applications; with the quality control systems in manufacture; with cooperative programs with industry and with other governmental agencies to assure the best use of all available resources; with the development of a cadre of agency personnel technically qualified to provide positive assistance to industry; and with information programs to physicians, other health professionals, and the general public when misinformation or ignorance seems to contribute to risk.

Edward Tuerk is Assistant Commissioner for Planning and Evaluation. He came to FDA in 1966 from the Public Health Service.



field reports

ATLANTA DISTRICT Chocolate Liquor, valued at approximately \$2,600, was seized at Murray Chocolate Co., Charlotte, N. C., because it contained live and dead insects and insects excreta. The chocolate had been held for more than a year in an insect- and rodent-infested plant.

A permanent injunction against two North Carolina egg firms and their president has been granted to prevent them from shipping adulterated and misbranded, unpasteurized frozen whole eggs in interstate commerce. Chick Haven Eggs, Inc., and Chick Haven Farms, Inc., North Wilkesboro, and Tam S. Hutchinson, president and general manager, were enjoined after Chick Haven Eggs shipped unpasteurized frozen whole eggs containing *Salmonella*.

BALTIMORE DISTRICT A pilot plan for industry self-certification was set up recently between a major food manufacturer and FDA. The agreement covers Jell-O Gelatin and Jell-O Golden Egg Custard Mix, two of the many products made at the General Foods plant in Dover, Del. The plan provides for sharing all pertinent records related to the two products. These include the firm's manufacturing evaluation and performance records, as well as qualitative formulas. FDA, in turn, will furnish the Dover plant with copies of any consumer or other complaints concerning either of the two products. FDA will also make available copies of any plant inspection reports necessary to carry out the objectives of the project. The 1-year plan, which went into effect September 1, will be monitored by the District.

BUFFALO DISTRICT The District made its first attempt in August to inspect under a warrant issued by the court, a new inspection procedure. The warrant was obtained after the owner of the Winton Co., Pittsburgh, Pa., refused three times to permit inspection of his food storage warehouse. The owner also refused inspection under the warrant. At a subsequent hearing, he agreed to an inspection. Before the proposed date, he entered a hospital, and after discharge he disappeared, leaving the warehouse closed. FDA is continuing to investigate the status of the warehouse.

DALLAS DISTRICT In the second injunctive action involving an exercise device manufactured in the Dallas, Tex., area, all but one of the persons involved agreed to a consent decree of permanent injunction.

The device had been marketed under such names as "Figure Control," "Electro-Tone," "Electro-Tone Figure Control," "Figure Control Electrosizer," and "Electrosizer." The FDA charged that the device is dangerous to health when used without medical supervision on individuals suffering from appendicitis, cancer, colitis, diverticulitis, hepatitis, peptic ulcer, arteriosclerosis, coronary disorders, hypertension, rheumatic heart disease, etc. On August 31, Arthur J. Sandone, Buford L. Coan, and Joe S. Falco, all of Consumer Electronics, Inc., agreed to the decree. Dan W. McCormick, doing business as Consumer Electronic Sales Co., has disappeared.

DETROIT DISTRICT Dow Corning Corp., Midland, Mich., and three officials were indicted on August 16 for violative shipments of a silicone fluid. The 16-count indictment charges interstate shipments of Dow Corning Medical Fluid 360, which was misbranded, since the labeling failed to bear adequate directions for use and the article was a new drug without an effective New Drug Application. The fluid has been used for treating the breasts.

KANSAS CITY DISTRICT A medicated feed, Russell Poultry Lift, was seized at I. D. Russell Co. Laboratories, Kansas City, Mo. Analysis revealed that the product contained only 55 percent of declared combined penicillin and was from an uncertified batch which was not exempt from certification.

LOS ANGELES DISTRICT A.C.N. Tablets, a vitamin preparation labeled with claims for treatment of acne, were seized in August at the manufacturer's plant, Person & Covey, Inc., Glendale, Calif. The bulk tablets, as well as labeled bottles, were seized on charges of false claims and inadequate directions for use in treating acne. The lot consisted of 2,275 labeled bottles; 1,942 unlabeled bottles; and about 600,000 bulk tablets, with a total value of \$52,000.

Meprobamate tablets labeled as the product of a New Jersey firm, but actually manufactured by Arizona Laboratories, Phoenix, were seized in August at Rocky Mountain Pharmacal Co., Phoenix, the distributor, and at another Phoenix dealer. Inspection of the Rocky Mountain firm showed that it had purchased the bulk powder and had the tablets manufactured in Phoenix. It used labels imitating those of the New Jersey firm, even to typeface and an actual control

number. Ballistic comparisons, however, showed the tablets had not been made in New Jersey. Seizure was based on the false label information and lack of full directions for use. Seized were 90 bottles of 500 tablets each, valued at \$1,175.

Seizure of the same drug was also made in Emeryville, Calif.

MINNEAPOLIS DISTRICT As the result of a consumer complaint about a phony medical practitioner, a fake diagnostic device was seized in Minneapolis, Minn., in July. The patient had gone to the practitioner because of a strained back muscle. The practitioner used a "Research Model" Toftness device to diagnose disease in the patient, and indicated that the device would pick up radiant energy from the body, which indicates something is wrong with the body.

The District and Mankato State College cosponsored a Consumer Problems Workshop at the college, July 5-8. Dr. Milton Huber, Center for Consumer Affairs, University of Wisconsin at Milwaukee; David Schoenfeld, Educational Consultant, President's Committee on Consumer Interests; and Blanche Erkel, Consumer Specialist, Minneapolis District, were consultants for the workshop. Sixty economics, health, and home economics teachers attended the workshop.

Minneapolis District hosted a State and Federal Workshop Program on Analytical Methodology for Pesticide Residues, Medicated Feeds, and Microbiology on September 6-8. Scientists from State regulatory agencies in Minnesota, North Dakota, South Dakota, and Wisconsin participated in the seminars and laboratory exercises. Subjects included sampling, analysis, and significance of findings.

NEW ORLEANS DISTRICT The District has examined large importations of brazil nuts recently. Eleven lots of brazil nuts, totaling 784,000 pounds and valued at \$176,383, were detained because of aflatoxin contamination.

NEW YORK DISTRICT Misbranded sex tablets were seized August 8. The 97,000 "Pro-Lon" tablets were promoted by the Male Health Clinic, New York, N. Y., the repacker and distributor, as an aid in the prevention of premature ejaculation during sexual intercourse. FDA alleged that the product, consisting of vitamins and antihistamines, was not an adequate and effective treatment for this condition.

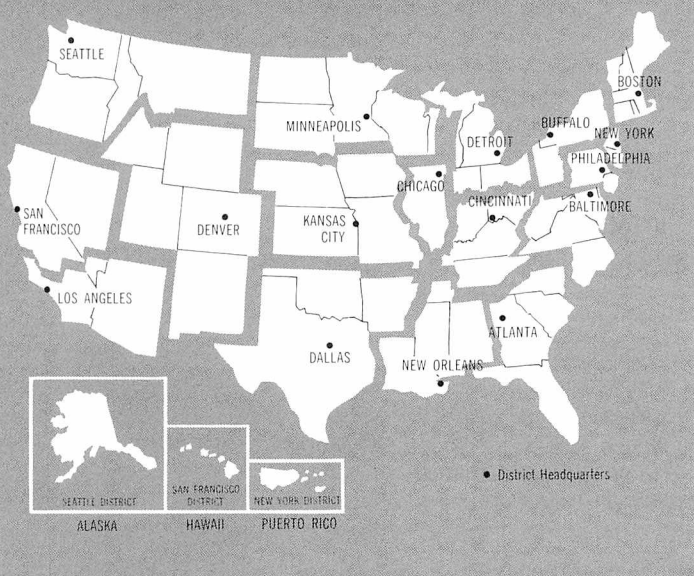
PHILADELPHIA DISTRICT A potentially hazardous oven cleaner containing propane was recalled from the market beginning in June. Aeroseal Corp., Camp Hill, Pa., voluntarily recalled its "Aeroseal Super Foam Oven Cleaner" from nationwide distribution. According to the company, a Los Angeles housewife later suffered severe burns in an explosion which occurred when she sprayed the cleaner in her oven. Similar incidents have been attributed to the use of two other oven cleaners, formerly sold by the Sunbeam Appliance Service Co., Chicago, Ill. FDA is checking the safety of other aerosol oven cleaners.

Routine inspection of a frozen pie manufacturer recently turned up *Salmonella* in a sample of creamed coconut. Followup at the manufacturer of the raw material, Durkee Famous Foods, Bethlehem, Pa., failed to show *Salmonella* in the lot of creamed coconut being manufactured at that time. When other Districts were alerted for further shipments of the product, New York District found *Salmonella* in one lot. Durkee initiated recall to the manufacturer level, including stocks in its warehouses in Bethlehem, Pa.; North Bergen, N. J.; and Louisville, Ky. Stocks were also located at several candy companies.

SAN FRANCISCO DISTRICT Due to misrepresentation and improper labeling, 150,000 meprobamate tablets, valued at approximately \$4,500, were seized August 29 at Interstate Laboratories, Emeryville, Calif. The tablets, some of which were falsely represented to be a well-known brand, were shipped from Phoenix, Ariz. The District was alerted to the shipment by Los Angeles District. The Interstate Laboratories owner stated that he bought the tablets from a man in the parking lot of the Hollywood Race Track, Los Angeles.

Due to the dangers caused by a label mixup involving castor oil bottles, the California Department of Public Health and FDA jointly issued a press release in August warning California consumers. An unknown number of 2-ounce bottles labeled "Vi-John Hospital Brand Castor Oil" were suspected to contain turpentine. Swallowing 2 ounces of turpentine could prove fatal. Distribution of the bottles by the Oakland, Calif., firm was limited to northern California. FDA first learned of the mixup when a consumer notified the District that he had found turpentine in one of

FOOD AND DRUG ADMINISTRATION DISTRICTS



the bottles. The company is voluntarily recalling all stocks in the hands of its distributors.

Imported venison contaminated with dirt, splinters, fly eggs, and maggots has been placed under detention. The New Zealand venison, weighing 125,000 pounds,

was valued at approximately \$70,000. The importer, Perky Jerky Brand, Morgan Hill, Calif., had hoped to start a new venture by making the venison into jerky. The boned venison was not subject to inspection by the USDA, as were the other jerky products put out by the firm. However, FDA sampled and examined the product. The owner of the firm indicated that he will not attempt to recondition the meat, but will go to New Zealand to try to improve operations at that end.

SEATTLE DISTRICT The Western Association of Food and Drug Officials held its annual meeting July 17-19 in Coeur d'Alene, Idaho. District Directors of the Los Angeles, Denver, and Seattle Districts were represented, as was FDA headquarters. Seattle District Director Franklin D. Clark was elected to serve on the executive board for the next year. Participants discussed mutual problems with cooperating officials from British Columbia, Washington, Oregon, Idaho, and Montana.

FDA DISTRICT OFFICES

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

BALTIMORE 900 Madison Avenue
Baltimore, Maryland 21201

BOSTON 585 Commercial Street
Boston, Massachusetts 02109

BUFFALO 599 Delaware Avenue
Buffalo, New York 14202

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

CINCINNATI 1141 Central Parkway
Cincinnati, Ohio 45202

DALLAS 3032 Bryan Street
Dallas, Texas 75204

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

DETROIT 1560 E. Jefferson Avenue
Detroit, Michigan 48207

KANSAS CITY 1009 Cherry Street
Kansas City, Missouri 64106

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

MINNEAPOLIS 240 Hennepin Avenue
Minneapolis, Minnesota 55401

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

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

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

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

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

FDA BUREAU OF DRUG ABUSE CONTROL FIELD OFFICES

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

BALTIMORE 401 Water Street
Baltimore, Maryland 21202

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

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

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

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

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

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

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

state actions

GMP Workshop Held A workshop on good manufacturing practices for drug manufacturers, repackers, and relabelers was held September 19 at the University of Wisconsin, Milwaukee. The University of Wisconsin School of Pharmacy, the University of Wisconsin Extension Service, and FDA sponsored the workshop.

Texas Finds Adulterated Eggs

The Texas State Department of Health's Division of Food and Drugs found 628 30-pound cans of adulterated frozen eggs at three plants and one cold-storage facility in August. At one plant, 227 cans were scheduled for voluntary destruction after *Salmonella* organisms were found. Legal action was instituted against the other two plants. One firm was fined \$125, but the charges were later dismissed. Litigation is still continuing in the second case. At the cold-storage facility, 159 cans sampled were found violative by organoleptic and laboratory examination. Since *Salmonella* was not detected, the lot was denatured and converted to animal feed.

Georgia and Florida Strengthen Drug Laws

Georgia and Florida have enforced new sections of their State food and drug laws. Georgia's amended Dangerous Drug Act, effective July 1, includes seizure and accountability sections, and authorizes the Board of Pharmacy to declare any drug as dangerous, including those declared so by the Food and Drug Administration. The Board has started recruiting more investigators to help carry out the law. An extension of the Florida Food and Drug Act, effective

July 10, deals with misbranding. Regulations are being promulgated.

Inspection Leads to Destruction

Joint inspection of a drug distributing firm led to voluntary destruction of all of the firm's stocks in August. FDA inspections had revealed that Medco Co., Inc., New Orleans, La., a part-time drug distributing firm owned by a number of physicians, had stocks of a variety of prescription drugs. The manager claimed he had no records to show the origins of the drugs; without evidence of interstate shipments, FDA could not institute seizures. Joint inspection with Louisiana State Food and Drug Inspector Louis Menendez revealed significant stocks of controlled drugs without any records of receipt, sale, or inventory. The manager decided to destroy all of the drug stocks

under State supervision. More than 250,000 tablets and capsules of amphetamine and barbiturate drugs, more than 383,000 tablets and capsules of miscellaneous potent drugs, and more than 28,000 suppositories were destroyed. Following the voluntary destruction, the firm went out of business.

Drug Auctions Regulated Stricter rules for sale of drugs at auction were approved by New York in August. An amendment to a New York State Board of Regents ruling restricts the sale of drugs in open containers to qualified pharmacy registrants, who must promptly remove the drugs to a pharmacy. This change places the responsibility for the quality of such drugs on the pharmacist. Previously, potent drugs in open containers were frequently purchased by liquidators or auctioneers who moved



Louisiana State Inspector Menendez supervises voluntary destruction of drugs.

them to a warehouse for resale. Various lots of drugs were often mixed, with insufficient regard for lot control numbers, expiration dates, and other factors important to the efficacy of the drugs.

Illegal Meat Ring Cracked As a result of raids on an illegal meat ring in September 1966, 16 Michigan individuals and firms have either pleaded or have been found guilty recently. The case involved butchering cattle that had died on farms of unknown causes and selling the meat for human consumption. Most of the convictions were for conspiracy to violate State agricultural laws, a felony which carries maximum penalties of 5 years in prison and a \$10,000 fine. The Michigan Department of Agriculture, the State Attorney General's Office, and the Michigan State Police cooperated in 5 months of undercover work leading to the arrests.

Canners Conference Held The Vegetable Canners Planning Conference for 1967 was held at Indianapolis, Ind., on August 1 and 2. Participants included representatives from the Illinois Department of Health, Ohio Division of Food and Dairies, Indiana Division of Food and Drugs, and Detroit and Cincinnati Districts. They discussed crop expectations and trends and planned inspections.

Sanitarian Training Program Held The University of Missouri, Columbia, held a course in environmental sanitation in July. Attending were sanitarians from local and State health agencies in six States. The Kansas City District presented a program for the sanitarians.



Boned meat taken in Grand Rapids during one of a series of raids on an illegal Michigan meat ring in September 1966. At work (l. to r.): State police detective; Robert Blackburn, food inspector; and Dr. Frank Carter, veterinarian, Michigan Department of Agriculture. Dr. Carter researched the dye that was injected into "planted" animals.

Contaminated Wheat Embargoed

Following a tip, Kansas City District confirmed that two cars of wheat originating in Lamar, Mo., and Cherryvale, Kans., were contaminated with the toxic weed seed *Crotalaria Sagittalis*. Further investigations revealed similar contamination in wheat from southeastern Kansas. Cooperation between FDA and the Kansas State Department of Health's Food Division led to State embargo of 13 carloads. The State is monitoring the reconditioning of all lots. The investigation indicated that the

contamination resulted from a wet season and subsequent late harvest.

Water Company Cited A Detroit water company was fined in August for selling bottled water with a high bacteria count. Panacea Water Co. had stated that it received the contaminated water from an Ohio company. But testimony from an FDA Inspector established that the firm was operating under insanitary conditions. The Detroit Health Department case consisted of five counts alleging that distilled water sold by the firm was misbranded.

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 105 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market were reported in July/August. These included 54 of foods: 2 because of poisonous and deleterious substances, 44 be-

cause of contamination, and 8 because of economic violations. Other seizures included 3 of vitamins and dietary foods, 33 of drugs (including 9 of medicated feeds), 12 of medical devices (including 3 of prophylactics), and 3 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Poisonous and Deleterious Substances		
Eggs, frozen, canned/Phoenix, Ariz. 6/29/67	Suncrest Poultry Farms, Inc./Phoenix, Ariz. (D)	Contain poisonous Salmonella micro-organisms.
Yeast, dried/Portage, Mich. 7/21/67	Lake States Div. St. Regis Paper Co./Rhinelander, Wis. (M,S)	"
Contamination, Spoilage, Insanitary Handling		
Anchovy fillets/Sun Valley, Calif. 8/3/67	Adolph Goldmark & Sons Corp./New York, N.Y. (S)	Excessive yeasty fermentation; swelled cans.
Cacao beans/Brooklyn, N.Y. 7/11/67	Produce Unitrade, Inc./New York, N.Y. (S)	Insect contaminated.
Cherries, Red Tart, pitted/Omaha, Nebr. 7/17/67	Fruit Growers Coop./Sturgeon Bay, Wis. (M,S)	Partly decomposed; abnormal odor.
Chocolate Mint candy/Provo, Utah 6/30/67	Jaffe Candy Co./Los Angeles, Calif. (M,S)	Prepared and packed under insanitary conditions; contains wood splinters, cloth fibers, metal fragments.
Liquor/Charlotte, N. C. 7/11/67	Murray Chocolate Co./Charlotte, N.C. (D)	Held under insanitary conditions; insect contaminated.
Coconut, desiccated/Atlanta, Ga. 7/5/67	Southern Bonded Warehouse Co./Atlanta, Ga. (D)	Rodent contaminated.
Corn, white/Maryville, Tenn. 8/15/67	Cloverhille Milling Co./Maryville, Tenn. (D)	Held under insanitary conditions; rodent contaminated.
bread mix/Milwaukie, Ore. 6/9/67	The Morrison Milling Co./Denton, Tex. (M,S)	Prepared and packed under insanitary conditions.
meal, yellow and white, degerminated/ Denver, Colo. 8/21/67	The Quaker Oats Co./St. Joseph, Mo. (S)	"
sirup solids, Dextrose, soy flour, sweet dough base/Dallas, Tex. 7/13/67	Shippers Warehouse Co./Dallas, Tex. (D)	Held under insanitary conditions; rodent contaminated.
Crabs, frozen, stuffed/Biloxi, Miss. 7/21/67	A.J. Bordelon Packing Co., Inc./New Orleans, La. (P,S)	Prepared and packed under insanitary conditions; excessive coliforms, high bacterial count.
Eggs, frozen/New York City, N.Y. 7/21/67	Producers Foods, Inc./New York, N.Y. (S)	Decomposed.
Lake City, Pa. 8/5/67	Sonny's Egg Marketing/Jamestown, N.Y. (M,S)	"
Flour/Tupelo, Miss. 7/3/67	J.J. Rogers & Son/Tupelo, Miss. (D)	Held under insanitary conditions.
Gainesville, Ga. 6/13/67	Carter Grocery Co., Inc./Gainesville, Ga. (D)	"
San Juan, P.R. 8/2/67	B. Fernandez & Hnos., Inc./San Juan, P.R. (D)	"
Bluffton, Ind. 8/23/67	The Lock Two Grain & Milling Co./New Bremen, Ohio (M,S)	Prepared and packed under insanitary conditions.
Garbanzos/San Juan, P.R. 8/28/67	Sinsheimer & Co. and Berger & Plate Co./San Francisco, Calif. (S)	Held under insanitary conditions; rodent contaminated.
Meal mix, self-rising/West Point, Ga. 8/8/67	Tallapoosa Milling Co./Tallahassee, Ala. (M,S)	Prepared and packed under insanitary conditions.
Milk, nonfat, dry, ice cream special blend/ Little Rock, Ark. 8/3/67	Coleman Dairy, Inc./Little Rock, Ark. (D)	Rodent contaminated.
Morrison's Korn-Kits/Milwaukie, Ore. 6/9/67	The Morrison Milling Co./Denton, Tex. (M,S)	"
Noodles, Foulds egg, Little Sport egg/ Indianapolis, Ind. 6/29/67	Regal Stores, Inc./Indianapolis, Ind. (D)	Held under insanitary conditions; insects.
Little Sport/Indianapolis, Ind. 6/29/67	"	"
Peas, dried black-eyed, navy beans, pinto beans, baby lima beans/Charleston, S.C. 8/11/67	Charleston Warehouse & Forwarding Co./Charleston, S.C. (D)	"
Peppers, pickled/Brooklyn, N.Y. 8/10/67	Red Rose Food Products, Inc./Perth Amboy, N.J. (D)	Prepared and packed under insanitary conditions; insect and maggot fragments.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Contamination, Spoilage, Insanitary Handling (cont'd)		
Pinto beans/Salinas, Calif. 6/23/67	Monterey Bay Suppliers/Salinas, Calif. (D)	Held under insanitary conditions; rodent contaminated.
Potato flakes/Lufkin, Tex. 7/27/67	Cooper Foods, Inc./Lufkin, Tex. (D)	"
Rice/Houston, Tex. 7/7/67	Blue Ribbon Rice Mills, Inc./Houston, Tex. (D)	" ; insects.
Salinas, Calif. 6/23/67	Monterey Bay Suppliers, Inc./Salinas, Calif. (D)	"
Savannah, Ga. 8/7/67	H. Traub's Sons, Inc./Savannah, Ga. (D)	"
San Juan, P.R. 8/2/67	Mendez Martinez & Co., Inc./San Juan, P.R. (D)	"
Shrimp, breaded, frozen/Chicago, Ill. 6/30/67	Morgan City Freezer & Cold Storage Co./Morgan City, La. (P,S)	Prepared and packed under insanitary conditions; staphylococci.
St. Louis, Mo. 7/31/67	"	"
Shrimpburgers, frozen/Mobile, Ala. 7/13/67	A.J. Bordelon Packing Co., Inc./New Orleans, La. (M,S)	"
Tomatoes, canned/St. Louis, Mo. 7/6/67	Markham Bros. & Co./Okeechobee, Fla. (S)	Contain fly eggs.
Suffield, Conn. 6/26/67	Homestead Canning Co./Homestead, Fla. (S)	"
Sunbury, Pa. 6/6/67	"	"
Wheat/Spokane, Wash. 6/27/67	J.C. Miller Elevator/Litchfield, N. Dak. (S)	Rodent contaminated.
Spokane, Wash. 6/16/67	Beach Coop Grain Co./Beach, N. Dak. (S)	"
Council Bluffs, Iowa 7/25/67	Farmers Cooperative Mercantile Co./West Point, Nebr. (S)	Insect-damaged kernels.
Spokane, Wash. 7/5/67	Wibaux Co-op Elevator Co./Wibaux, Mont. (S)	Rodent contaminated.
Seattle, Wash. 8/8/67	Farmer's Union Grain Terminal/Valier, Mont. (S)	"
Superior, Wis. 8/16/67	Humboldt Elevator Association/Humboldt, Minn. (S)	"
Pendleton, Oreg. 8/26/67	Parma Seed, Inc./Notus, Idaho (S)	"
Economic Violations		
Fruit Punch, Grape Drink, Orange Drink, Pineapple-Grapefruit Drink, Orange-Apricot Drink/Aurora, Ill. 6/20/67	M. Steffen & Co./Coloma, Mich. (M,S)	Below declared vitamin C content.
Herring fillets in sauce/Bronx, N.Y. 7/6/67	Reese Finer Foods, Inc./Bronx, N.Y. (D)	False and misleading vignette and label "in lobster sauce"; sauce is made of crayfish and contains no lobster meat.
Noodle-Roni/Yorktown, Ind. 7/27/67	Golden Grain Macaroni Co./Bridgeview, Ill. (M,S)	False and misleading label "Chick'n Almond Sauce Mix"; contain little or no chicken meat.
Nuts, mixed/Dayton, Ohio 7/21/67	Pittsburgh Snax Co., Inc./Pittsburgh, Pa. (M,S)	False and misleading vignette depicting substantial quantities of nuts other than peanuts, including pecan nut meats; contain no pecan nut meats, mainly peanuts.
Orange juice, frozen/Phoenix, Ariz. 6/29/67	Associated Grocers/Phoenix, Ariz. (D)	Below standard quality for frozen orange juice.
Bronx, N.Y. 8/8/67	Frozen Fruit Concentrates, Inc./Bayamon, P.R. (M,S)	" ; contains a nonnutritive artificial sweetener, sodium cyclamate.
Tea bags/Dorchester, Mass. 6/22/67	New England Tea Packing Co., Inc./Dorchester, Mass. (D)	Short weight.
Tomatoes, canned/Oklahoma City, Okla. 7/11/67	Elsa Canning Co./Elsa, Tex. (M,S)	Below standard quality for canned tomatoes.
Vitamins—Dietary Food		
Liver & Iron Capsules/Yonkers, N.Y. 7/25/67	Nyal Co., Inc./Yonkers, N.Y. (D)	Below declared amount of vitamin B ₁₂ .
Prol-Ade Water Dispersible Vitamins/Great Falls, Mont. 6/20/67	Wittney & Co./Denver, Colo. (M,S)	Below labeled strength; not in conformity with good manufacturing practices.
Woltrinsic Capsules, Every Day Chewable Vitamins/Farmingdale, N.Y. 7/7/67	Garden Laboratories, Inc./Hackensack, N.J. (M,S)	Below labeled strength; deficient in vitamin B ₁₂ .
DRUGS / Human Use		
A.C.N. Tablets/Glendale, Calif. 7/28/67	Person & Covey, Inc./Glendale, Calif. (D)	False and misleading claims to treat acne; inadequate directions for use.

SEIZURE ACTIONS

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
DRUGS /Human Use (cont'd)		
Ahead Hair Restorer/Pittsburgh, Pa. 6/19 and 7/3/67	Kelly Products, Inc./Royal Oak, Mich. (M,S)	New drug not approved for safety and efficacy.
Ammonium Chloride Tablets/Brooklyn, N.Y. 8/10/67	Plymouth Laboratories/Plymouth, Mich. (M,S)	Below USP standard.
Aspirin/Los Angeles, Calif. 7/5/67	Los Angeles County Health Dept./Los Angeles, Calif. (D)	Fails to disintegrate.
Comedonen Wasser, Azulen-Hy-Ol-Haut Teint Royal Hair Tonic, Krauter Komplex/ Miami, Fla. 6/29/67	Dr. Babor & Co./Aachen, Germany and Laboratorium Aphia/Schwarzwald, W. Germany (M,S)	False and misleading claims for treatment of itchy skin, sunburn, acne, fungi, eczema, scars, chronic loss of hair, excessive dandruff.
Cougar After Shave Lotion/New York, N.Y. 8/4/67	Youth Cosmetics (Information, Inc.) New York, N.Y. (D)	False and misleading claims to prevent aging of skin, wrinkles, bags under the eyes.
Derma-R _x Lotion/Frazier, Pa. 7/7/67	Hart Laboratories, Inc./Clemmons, N.C. (M,S)	Inadequate directions for use and inadequate warnings against use in pathological conditions.
Droga Cleansing Milk, Droga Creamy Soap, Droga Tonic, Nourishing Gel, Azulen Cream/Glendale, Calif. 7/10/67	Les Grands Parfums De France/Lynn, Mass. (S) Imported from Germany	False and misleading claims to make your skin healthy.
Encifort Tonico/Hato Rey, P.R. 7/5/67	Dorasol Laboratories, Inc./Hato Rey, P.R. (D)	False and misleading claims to prevent and treat pyorrhea, gingivitis, and other pathological manifestations of the gums and teeth.
Eye Bath/Washington, D.C. 6/19/67	E.C. DeWitt & Co., Inc./Chicago, Ill. (M,S)	Below labeled purity and quality; nonsterile.
Gold Daigaku Eye Drops, Utsu Kyumeigan Baby Pills/Los Angeles, Calif. 4/12/67	Product of Japan. Fujiya Trading Co., Osaka, Japan and Crown Trading Co., Kobe, Japan (S)	False and misleading claims to revitalize, rejuvenate, retard aging of eye tissue, help prevent hardening of cells and tissues of the eye; to be effective for food poisoning, heat strokes, bedwetting, diarrhea, dizziness.
Hydrogen Peroxide Solution USP/Rochester, N.Y. 7/26/67	Berke Chemical Co./Detroit, Mich. (M,S)	Does not conform to USP standard; contains nitrobenzene.
Liver Protein Fraction/Kalamazoo, Mich. 7/18/67	The Upjohn Co./Chicago, Ill. (S)	Contains poisonous Salmonella micro-organisms.
Lust's, Dr. B., Herb Pills #3/Bronx, N.Y. 8/8/67	Benedict Lust Publications/New Canaan, Conn. (M,S)	False and misleading claims to relieve headaches, bloated feeling, gas, drowsiness, bad taste in mouth, nervousness, constipation.
Meprobamate 400 mg Tablets/Phoenix, Ariz. 8/9/67 (2 actions)	In part: Arizona Labs., Inc./Phoenix, Ariz.; Riverton Labs., Inc./Newark, N.J. (M,S)	Not in conformity with required labeling information; no caution statement.
Parktension Tablets, Geriatric Tablets/ Wilmington, Del. 5/25/67	Milan Pharmaceuticals, Inc./Morgantown, W. Va. (M,S)	Below declared amounts of ascorbic acid and methyltestosterone, respectively.
Percodryl-A/Hato Rey, P.R. 7/5/67	Joaquin Belendez Sola, Inc., d/b/a Delta Pharmaceuticals, Inc./Hato Rey, P.R. (D)	Below declared amounts of theophylline and phenylephedrine.
Piperazine Citrate Syrup/Rio Piedras, P.R. 8/2/67	Laboratories Sein, Inc./Rio Piedras, P.R. (D)	Below USP standard.
Prenatob Prenatal Tablets/Columbus, Ohio 7/18/67	International Food and Drug Corp./Fort Wayne, Ind. (S)	Contain cobalt sulfate, a food additive not in conformity with regulations; deficient in vitamin C.
Pro-Estrone, Dipyrone, Pentobarbital, Dextro-amphetamine/San Gabriel, Calif. 8/3/67	Bio Products Research Lab./Tempe, Ariz.; Austin Pharmaceutical, Inc./Long Island, N.Y. (M,S)	No full disclosure labeling; no approved NDA.
Una-Trim tablets/Hollywood, Fla. 5/16/67	Imperial Sales Co./Hollywood, Fla. (D)	False and misleading claims as an aid in weight control and appeasing the appetite; below labeled quality.
Viro-Zyme injection, Niaocin injection, Myo-X injection and capsules, Lipo K w/ Heparin, Lipo K injection, capsules and tablets, Ossionate-25 injection, Ossionate capsules, Ossionate Plus capsules, Normotensin injections and tablets, Pla-C-Don injection and tablets, Pre-Nin Plus Fluoride tablets, Aminogen injection, Reglobenol injection/Los Angeles, Calif. 8/3/67	Marcen Laboratories, Inc./New Rochelle, N.Y. (M,S)	New drugs not approved for safety and efficacy; not in conformity with required labeling information; false and misleading claims.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Veterinary / Medicated Feed		
Fossil Shell Flour (Mineral Feed Supplement)/Lubbock, Tex. 7/19/67	Perma-Guard Corp./Phoenix, Ariz. (M,S)	False and misleading claims for hookworms in dogs, large roundworms in horses, ticks, yellow mucous in calves, arthritis and rheumatism in horses and dogs, worms in sheep and goats.
Geisler Medicated Food, Bird Ointment, Soothe-Aid, Pet Care books/Caldwell, N.J. 7/31/67	Geisler Pet Products/Bronx, N.Y. (M,S)	Below labeled quality; false and misleading claims to treat diarrhea, enteritis, dysentery; hoarseness, pneumonia, wheezing, bare spots, bald heads, sore feet and legs; medicated food contains bismuth subnitrate in excess of declared amount; bird ointment is deficient in iodine.
Kaff-A Milk Replacer For Calves/Omaha, Nebr. 7/13/67	Kraft Foods/Chicago, Ill. (M,S)	Contains chlortetracycline and oxytetracycline, food additives not in conformity with regulations; not certified; false and misleading claims for prevention of scours.
Medicated Feed/Knoxville, Tenn. 8/30/67	The James Mill/Knoxville, Tenn. (M,S)	Inadequate directions and inadequate warnings.
Pay Way 20% Hi-Energee Ruminant Supplement/Hutchinson, Kans. 8/3/67	Pay Way Feed Mills/Kansas City, Mo. (M,S)	Below labeled strength; deficient in chlortetracycline.
Sulfa-Trol Pellets/Griffin, Ga. 8/10/67	Bingman Laboratories, Inc./Caldwell, Ohio (M,S)	Below labeled strength and quality; deficient in sodium sulfathiazole; inadequate directions and warnings that a veterinarian should be consulted if no improvement after 2 or 3 days is noted.
Sup'r-Sav'r Feed Mix/Birmingham, Ala. 8/3/67	Bingman Laboratories, Inc./Caldwell, Ohio (M,S)	False and misleading labeling for use of malathion fly bait, but article is not malathion fly bait.
2,6, diiodo, 4-nitrophenol solution/Oklahoma City, Okla. 7/11/67	Curtis Laboratories, Inc./Kansas City, Mo. (M,S)	New drug not approved for safety and efficacy.
Universal Super-Ten Feed Concentrate/Delano, Minn. 6/9/67	Universal Shell Co./Muscatine, Iowa (M,S)	Not manufactured in conformity with good manufacturing practices; contains less EDDI than claimed on label.
MEDICAL DEVICES		
Arlo Lady Bust Massage/Miami, Fla. 6/29/67	Arlo Lady/Pesseux, Switzerland (M,S)	False and misleading claims to increase fullness of bust.
Electronic Analysis Instrument Model F/Cambridge Springs, Pa. 6/26/67	Merritt W. Terrell, D.C./Cambridge Springs, Pa. (D)	Inadequate directions for use; adequate directions cannot be written since device is worthless for any medical use.
Electronic Exerciser, Trimex/Arlington, Va. 8/29/67	Dyna Trim & Trimex Corps./Bethesda, Md. (M,S)	False and misleading claims to reduce hips, waistline and thighs; exercise and massage.
Syringes, disposable/Chattanooga, Tenn. 8/2/67	Elgin Syringe Corp./Elgin, Ill. (M,S)	Label statements "sterile" and "pyrogen free" are false and misleading; product contains tears, punctures, and incomplete seals.
Buffalo, N.Y. 8/10/67	"	"
Tyler, Tex. 8/24/67	"	"
Toftness Research Model/Columbia Heights, Minn. 7/18/67	Leo R. Majewski/Columbia Heights, Minn. (D)	Inadequate directions for use; adequate directions cannot be written since device is worthless for diagnoses in man.
Vapozone Generator/North Hollywood, Calif. 7/20/67	The Crown Room/North Hollywood, Calif. (D)	False and misleading claims regarding hair growth.
Sherman Oaks, Calif. 8/1/67	Beauty Unlimited/Sherman Oaks, Calif. (D)	"
Prophylactics		
Rubber/Akron, Ohio 7/6/67	Akwell Industries, Inc./Dothan, Ala. (M,S)	Defective; holes.
Atlanta, Ga. 7/27/67	Killashun Sales Div. of Akwell Industries/Dothan, Ala. (M,S)	"
Searcy, Ark. 7/12/67	M & M Rubber Co./Kansas City, Mo. (M,S)	"

SEIZURE ACTIONS

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
HAZARDOUS SUBSTANCES		
Mar-Go Furniture Finish Restorer/Tacoma, Wash. 7/5/67	Market Development Associates, Inc./Tacoma, Wash. (M,D)	Lacks consumer protection information required by the Fed. Hazardous Substances Act.
Rag Dolls/Moonachie, N.J. 7/14/67	Imported from Poland by Viking Import Trade, Inc./Moonachie, N.J. (S)	Highly flammable.
Thoro Dry Cleaner/Salt Lake City, Utah 8/23/67	Thoro Products Co./Arvada, Colo. (M,S)	Lacks consumer protection information required by the Fed. Hazardous Substances Act.

POST OFFICE DEPARTMENT

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

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

July 21, 1967: Fraud Order against **Paul James**, P.O. Box 2313, N. Grand Central Station, New York, N.Y.
Promoter used the mails to advertise and obtain remittances for a booklet titled "The Natural Hair Formation System," which was represented as revealing a positive cure for male and female baldness.

August 24, 1967: Fraud Order against **Robert Curtiss**, Calgary, Alberta, Canada.
This promoter advertised that he provided absent healing treatments to renew the physical organs of the body and that

distance was no factor. Curtiss requested that a love offering be sent with the request for healing.

September 6, 1967: Fraud Order against **Stein's Manufacturing Co.**, Woodbury, N. J.
Advertisements offered Stein's Strength & Vigor Methods to overcome fading strength and vigor. A free supply of Complemin tablets, a vitamin-mineral preparation, was included with the "Methods." The "Methods" were offered without cost with the hope those to whom they were sent would continue to order the Complemin tablets. Needless to say, neither of the products, singly or in combination, would increase sexual prowess.

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

July 27, 1967: **Derf Merchandising, Inc.**, 199 Merrick Road, Lynbrook, N. Y.
Using the mails to advertise and obtain remittances for a product called "Mate-Herb" represented as a sex stimulant and aphrodisiac "Recommended by World Famous Physicians" and "U.S. Department of Commerce Consular Report," "British Medical Journal," etc.

September 13, 1967: **S. I. Research**, Hollywood, Calif.
Solicitations of orders and sales through the mails of a pamphlet describing silicone implants to enlarge the female bust.
September 13, 1967: **National Health**, Los Angeles, Calif.
Solicitations of orders and sales through the mails of a booklet describing exercises alleged to increase the female bust-line in 15 days.

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

Twenty-two persons were indicted by Federal grand jury, Sioux City, Iowa, on July 13, 1967, charged with 15 counts of mail fraud, six counts by wire and one count of conspiracy. The defendants are chiropractors and chiropractic students. Principal defendants are charged with securing the test questions in advance of the examinations to be given by Basic Science Boards in various States throughout the country, including Iowa, Nevada, Utah, Illinois, and South Dakota. They are alleged to have thereafter charged fees up to \$3,000 to students of chiropractice schools desiring to obtain licenses to practice in those States.

On August 8, 1967, **Edward I. Winkler** was found guilty by jury, at Los Angeles, Calif., on nine counts of mail fraud. Sentencing set for September 18. Defendant did business as **VIB-ERECT CO.**,

in the nationwide advertising and sale of a "sex aid device" falsely represented as helpful to the impotent male. Winkler mailed 50,000 advertising brochures and grossed \$30,000 within a few months period. The device, which he sold for \$25 each, was merely a battery-operated facial massage instrument purchasable at many cosmetic counters for \$1.35 each.

On September 15, 1967, **Myron Wisotsky, d/b/a The Myconol Co.**, Freehold, N. J., and **Hardwick Shaw Co.**, New York, N. Y., was fined \$1,000 in Federal court in Newark, N. J., and placed on probation for 3 years for mail fraud. The estimated amount filched from the public in the sale by mail of Myconol Capsules and Orotex Capsules, sold as weight-reducing products, exceeded \$300,000.

notices of judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

Drink mix, at Memphis, W. Dist. Tenn.

Charged 8-24-66: when shipped by Farmers Cooperative Creamery Co., Ogilvie, Minn., the article, labeled in part "Baker's Brand Regular Whip Chocolate Flavor Vending Mix . . . General Foods Corporation . . . White Plains, New York," contained the added poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). Default decree ordered destruction. (1)

Peanuts, unshelled, at Walla Walla, E. Dist. Wash.

Charged 1-5-66: while held by Walla Walla Produce Co., Walla Walla, Wash., the article was held under insanitary conditions, and its container was composed wholly or in part of the poisonous and deleterious substance DDT; 402(a)(4), 402(a)(6). Consent decree authorized release to dealer for salvaging. (2)

FOOD / Contamination, Spoilage, Insanitary Handling

Apples, dried, Triton, Southern Special, and Empire, 2 seizures at Louisville, W. Dist. Ky., and at Elk Grove Village and Chicago, N. Dist. Ill.

Charged 1-6-66 and 2-16-66: when shipped by Valley Evaporating Co., Wenatchee, Wash., the article contained insect and rodent filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decrees authorized release to shipper for salvaging. (3)

Barley, at Chicago, N. Dist. Ill.

Charged 10-7-66: when shipped by H. C. Knoke & Co., Chicago, Ill., to Paris, Tex., and thereafter returned, the article had been prepared, packed, and held under insanitary conditions; 402(a)(4). Consent decree authorized release to shipper for reconditioning and conversion to dog food. (4)

Beans, mung, at San Francisco, N. Dist. Calif.

Charged 8-17-65: while held by Nan King Noodle Factory, San Francisco, Calif., the article contained rodent and insect filth, and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (5)

Candy, pecan pralines, Kitty's Kandy Kitchen, at Fort Scott and Lawrence, Dist. Kans.

Charged 10-12-66: when shipped by Kitty's Kandy Kitchen, Oklahoma City, Okla., the article contained insect filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (6)

Cornhusks, dried, at New Orleans, E. Dist. La.

Charged 7-6-66: when shipped by George Walchar, Weimar, Tex., the article contained insect filth and moldy cornhusks; 402(a)(3). Default decree ordered destruction. (7)

Eggs, frozen, at Baltimore, Dist. Md.

Charged 1-26-66: when shipped by Olson Bros., Inc., La Habra, Calif., the article contained decomposed eggs; 402(a)(3). Default decree ordered destruction. (8)

Fennel seeds, at Chicago, E. Dist. Ill.

Charged 12-3-65: while held for sale, the article contained insect and rodent filth; 402(a)(3). Consent decree authorized release to Archibald & Kendall, Inc., Chicago, Ill., for reconditioning. (9)

Flour, at Newport News, E. Dist. Va.

Charged 6-23-66: while in transit, the article contained decomposed flour and had a musty odor, since it had been subject to rainwater from a leaking railcar; 402(a)(3). Consent decree authorized release to the Chesapeake & Ohio Railroad Co., Newport News, Va., for salvaging. (10)

Flour, rice, and cornmeal mix, at Lancaster, Dist. S.C.

Charged 10-17-66: while held by Plyler Wholesale Co., Inc., Lancaster, S.C., the articles contained insect filth, and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (11)

Nuts, mixed, 2 seizure actions at Detroit, E. Dist. Mich.

Charged 2-2-66 and 3-9-66: while held for sale, the articles contained insect filth, and moldy, rancid, decomposed, and shriveled nuts and/or empty shells; 402(a)(3). Consent decrees authorized release to B & S Produce Co., Detroit, Mich., for reconditioning. (12)

Peaches, canned, at Carlsbad, Dist. N. J.

Charged 11-18-64: while held for sale, the article contained a decomposed substance; 402(a)(3). Consent decree authorized release to George Norioan, t/a Norioan Co., Dinuba, Calif., for segregation. (13)

Popcorn, at Houston, S. Dist. Tex.

Charged 10-17-66: while held by Texas Union Warehouse Co., Houston, Tex., the article contained insect filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (14)

Potatoes, frozen, at Grand Rapids, W. Dist. Mich.

Charged 8-19-66: when shipped by Interstate Potato Packers Corp., Nampa, Idaho, the article, labeled in part "Spartan Loose . . . Hash Brown Pan Ready Potatoes Ranch Style . . . Distributed by Spartan Stores, Inc., Grand Rapids, Mich.," contained *E. coli* and bacterial filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (15)

Rice, at Los Angeles, S. Dist. Calif.

Charged 7-22-66: while held by American Warehouse, the article contained filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (16)

Shrimp, breaded, frozen, 2 seizures at Syracuse, N. Dist. N. Y., and Buffalo, W. Dist. N. Y.

Charged 9-16-66 and 10-5-66: when shipped by National Shrimp Processors, Inc., Brownsville, Tex., the article, labeled in part "Chicken of the Sea Round (or 'Butterfly') Breaded Shrimp . . . Distributed by Van Camp Sea Food Co., Div. Ralston Purina Co., Port of Long Beach, California," contained *E. coli*, bacterial filth, and staphylococci; and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4).

Default decree ordered destruction. (17)

Shrimp, breaded, frozen, at New Orleans, E. Dist. La.

Charged on or about 1-26-67: when shipped by Henderson's Portion Pak, Coral Gables, Fla., the article, labeled in part "National Pride Breaded Products Butterfly Tail Off Shrimp . . . Packed By National Pride Coral Gables, Fla.," contained coagulase positive staphylococci and bacterial filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (18)

Shrimp, breaded, stuffed, 3 seizure actions at Carnegie, W. Dist. Pa., Des Moines, S. Dist. Iowa, and Albuquerque, Dist. N. Mex.

Charged 10-4-66, 9-29-66, and on or about 10-3-66: when shipped by Booth Fisheries Corp., Brownsville, Tex., the article contained insect filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decrees ordered destruction. (19)

Sorghum and corn sirup, Old Kentucky Home, at Grand Rapids, W. Dist. Mich.

Charged 3-1-67: when shipped by Kentucky Sorghum Growers' Cooperative Association, Hawesville, Ky., the article contained insect and rodent filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered delivery to charitable institution for use as animal feed. (20)

Strawberries, frozen, and blueberries, frozen, at Chicago, N. Dist. Ill.

Charged 10-25-66: while held for sale, the articles contained decomposed berries; 402(a)(3). Default decree ordered destruction. (21)

Tomato juice, canned, at Tulsa, N. Dist. Okla.

Charged 10-13-66: when shipped by Texsun Corp., Weslaco, Tex., the article contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (22)

FOOD / Economic Violations

Basil and oregano, Leone Di Marco, at Pittsburgh, W. Dist. Pa.

Charged 12-26-65: while held by Sausage Manufacturing Co., Inc., Pittsburgh, Pa., the articles, after being repacked and labeled by the dealer, were short weight (approx. 12 and 27 percent, respectively); 403(e)(2). Consent decree authorized release to dealer for repacking and relabeling. (23)

Beans, green, cut, canned, Deck's, at Indianola, N. Dist. Miss.

Charged on or about 4-28-66: when shipped by Allen Canning Co., Siloam Springs, Ark., the article contained excess fibrous material; 403(h)(1). Default decree condemned the article which had already been destroyed by a warehouse fire. (24)

Beans, green and wax, cut, canned, Kant-Miss, at St. Paul, Dist. Minn.

Charged 3-17-66: when shipped by Marshfield Canning Co., Marshfield, Wis., pieces of bean pod tested less than 3/4 inch in length, exclusive of shorter end pieces of pod; and the labeling, which made special dietary claims for weight control, lacked required information concerning special dietary use; 403(g)(1), 403(j). Consent decree authorized release to shipper for relabeling. (25)

Cheese, swiss, at Louisville, N. Dist. Ohio.

Charged 6-30-66: when shipped by Fairview Swiss Cheese Co., Fredonia, Pa., milk fat had been in part omitted or abstracted from the article, and the article's solids lacked the required 43 percent milk fat; 402(b)(1), 403(g)(1). Consent decree authorized release to Biery Cheese Co., Louisville, Ohio, for reconditioning. (26)

Cookies, chocolate flavored, at North Kansas City, W. Dist. Mo.

Charged 7-1-66: when shipped by Bake-Line Products, Inc., Des Plaines, Ill., the article was labeled in part "Oven Gold Chocolate Flavored Sandwich Cookies Net Wt. 14 oz. Distributed by American Bakeries Company . . . Chicago, Illinois," but the distributor's name and place of business and quantity of contents were inconspicuous, since the printing was in dark-brown ink on a clear cellophane package containing dark-brown cookies; 403(f). Default decree authorized donation to public/charitable institution. (27)

Imitation margarine, Demi, at Albany, N. Dist. N. Y.

Charged 7-15-64: when shipped by Frenchette, Div. of Carter Products, Inc., Cranbury, N. J., a compound, having a consistency similar to that of butter, containing oils or fats other than milk fat, and made in imitation or semblance of butter but with less than 80 percent fat, had been substituted for standardized margarine which the article purported to be; and the article failed to conform to the standard of identity for margarine, because of low fat and the presence of ingredients not permitted by the standard; 402(b)(2), 403(g)(1). The article was claimed by the shipper and the charges contested. As stated by the court, the position of the Government was that the article violated the law because Congress declared that all products made in semblance of butter were to be called "margarine," that there should be but one imitation of butter, and that imitations of butter which must be called "margarine" must, in all cases, comply with the standard of identity for margarine. The court agreed with the claimant that the Conference Report of Congress on the 1950 Oleomargarine Amendments placed oleomargarine or butterlike products primarily under advertising controls. The court could find nowhere that margarine was to be considered solely as the one product that was imitation butter, and felt that imitation margarine was further removed from the area of possible misrepresentation than margarine would be. The court found that there could be no legal compulsion placed upon the claimant to petition administratively for a new standard for margarine or an amendment to the original standard; granted the claimant summary judgment; and dismissed the libel. (28)

Tomatoes, canned, Pine Cone, at Amsterdam, N. Dist. N. Y.

Charged 7-8-66: when shipped by Albert W. Sisk & Son, Preston, Md., the article contained excess peel; 403(h)(1). Consent decree authorized release to shipper for relabeling. (29)

Tunafish, canned, at Brooklyn, E. Dist. N. Y.

Charged 5-11-66: when shipped by IBEC Packing Co., Inc., Mayaguez, P.R., the article fell below the required standard of fill for tunafish, since the average weight of pressed cakes of the solid pack tuna was less than that prescribed; 403(h)(2). Consent decree authorized release to Dagim Tahorim Co., Brooklyn, N. Y., for reconditioning. (30)

FOOD AND COLORING ADDITIVES

- Food coloring, and plums, pickled, Aka-Ume**, at Los Angeles, C. Dist. Calif.
Charged 12-28-66: while held by Mutual Trading Co., Inc., Los Angeles, Calif., the food coloring was a nonconforming color additive, an uncertified coal-tar color not listed for use in food—402(c), 706(a); bulk plums contained insect and rodent filth—402(a)(3); and plums repacked by the dealer contained insect and rodent filth and the nonconforming color additive; and the labeling of repacked plums made false and misleading claims of Japanese origin, lacked the common or usual name of each ingredient, and failed to declare the artificial coloring—402(a)(3), 402(c), 403(a), 403(k), 706(a). Default decree ordered destruction. (31)
- Ice balls**, at Cleveland, N. Dist. Ohio.
Charged 5-2-66: when shipped from Hong Kong by unknown shipper, the article, an easily punctured or cracked thin plastic ball containing a leaking fluid with green algae, viable micro-organisms, insect fragments and plant fiber, was a food additive, and its uses and intended uses lacked conformity with the law; 402(a)(2)(C), 409. Default decree ordered destruction. (32)
- Ice balls and ice elephants**, at Chicago and Aurora, N. Dist. Ill.
Charged 6-29-66: when shipped by South Sea Trading Co., Ltd., and Sanyei Corp., Ltd., Hong Kong, China, and by Hiraoka & Co., Ltd., Tokyo, Japan, the articles, labeled in part "Frosty Drink Coolers . . . Unique Products, Chicago, Ill. . . Made in Hong Kong," "Devil Balls of Ice . . . Japan," or "Ice Balls Made in Hong Kong," were nonconforming food additives (they were thin, leaky, easily punctured or cracked, plastic articles containing a fluid at their centers which contained miscellaneous debris and viable micro-organisms); 402(a)(2)(C), 409. Default decree ordered destruction. (33)
- Ice elephants, plastic**, at Seattle, W. Dist. Wash.
Charged on or about 5-3-66: when shipped by Sterling Novelty Products (Div. of Glovemakers, Inc.), Chicago, Ill., the article was a nonconforming food additive, since the plastic was easily punctured or cracked and the fluid within contained viable micro-organisms and miscellaneous debris; 402(a)(2)(C), 409. Default decree ordered destruction. (34)
- Ice stirrers, ice elephants, ice balls, and ice cubes**, at Long Island City, E. Dist. N. Y.
Charged 4-27-66: when shipped by Sterling Novelty Products, Chicago, Ill., the articles, labeled in part, "Ice/N Stir for 'Ice balls' or 'Ice cubes,'" manufactured . . . Hong Kong . . . Rovel Co., Long Island City, New York," were nonconforming food additives (they were thin, easily punctured or cracked plastic articles containing a fluid inside with mold, debris, and micro-organisms); 402(a)(2)(C), 409. Default decree ordered destruction. (35)

ANIMAL FEEDS

- Banner milk replacer**, at Amery, W. Dist. Wis.
Charged 3-23-66: when shipped by Jersee Security Food Co., Minneapolis, Minn., the article, labeled in part "Banner Milk Replacer . . . Medicated . . . Active Drug Ingredient: Chlortetracycline HCL . . . Manufactured by Northern Supply Company, Amery, Wisconsin," contained false and misleading claims for the prevention, when fed as directed, of bacterial diarrhea in calves, and the article lacked antibiotic batch certification and was not exempt therefrom, since the article failed to provide enough chlortetracycline for the prevention of bacterial calf diarrhea; 502(a), 502(l). The article was claimed by the shipper. Upon the pleadings and claimant's letter, summary judgment was granted to the Government; the article was ordered destroyed or delivered to public/charitable institution, with advice concerning its ineffectiveness as a drug. (36)
- Bingman's Sup'r-Sav'r swine and poultry medicated feed**, at Griffin, N. Dist. Ga.
Charged 5-4-66, amended on or about 8-4-66: when shipped by Bingman Laboratories, Inc., Caldwell, Ohio, the article was deficient in penicillin (approx. 40 percent) and bacitracin (approx. 50 percent), and its labeling was false and misleading as to content; 501(c), 502(a). On 6-1-66, the article was claimed by the dealer. On 7-5-66, the court denied claimant's motion for a change of venue, saying: "This Court has no power to transfer to another federal district a condemnation proceeding by the United States under the Federal Food, Drug, and Cosmetic Act where the proceedings charge both adulteration and misbranding. *Clinton Foods, Inc. v. Moore*, 188 F. 2d 289 (C. A. 4, 1951). *Fettig Canning Co. v. Steckler*, 188 F. 2d 715 (C. A. 7, 1951)." Thereafter, the claimant failed to answer the Government's interrogatories, and a default decree of condemnation was entered ordering the article destroyed. (37)
- Kentucky Farm medicated pig grower**, at Caneyville, W. Dist. Ky.
Charged 5-4-66, amended 5-9-66: while held by Caneyville Roller Mills, Caneyville, Ky., the article, which had been manufactured by the dealer from ingredients shipped in interstate commerce, was deficient in strength and its label false and misleading as to arsanilic acid content, since none of the declared arsanilic acid was present in the article; 501(c), 502(a). Default decree ordered destruction. (38)
- Mor-Gain 26% Grain balancer, and Mor-Gain Special egg mash**, at Mason City, N. Dist. Iowa.
Charged 5-16-66: while held by Northwestern Distributing Co., Inc., Mason City, Iowa, the article, which had been manufactured by the dealer from an arsanilic acid premix shipped in interstate commerce, contained the food additive arsanilic acid, and it and its intended use failed to conform to regulation or exemption, since the article was intended to be fed separately with grain to laying hens; 402(a)(2)(C). Consent decree authorized release to dealer for relabeling. (39)

DRUGS / Human Use

- Allergimist intranasal solutions A and B**, at Los Angeles, S. Dist. Calif.
Charged 6-16-66: when shipped by Allergimist, Inc., Miami Springs, Fla., the articles, labeled in part "Allergimist Solution . . . Hydrolosate of Nucleo-Proteins . . . Curative Intra-Nasal Solution . . . Distributed by the Brunson Corporation . . . Miami, Fla.," were new drugs without effective approved New Drug Applications; 505(a). Default decree ordered destruction. (40)
- Allergimist intranasal solutions A and B**, 2 seizures at Waco, W. Dist. Tex.
Charged on or about 4-20-66 and on or about 5-2-66: when shipped by Brunson Corp., Miami Springs, Fla., the articles were new drugs without effective approved New Drug Applications; 505(a). The shipper claimed the articles. Requests for admissions and written interrogatories were served on the claimant. There was no response by the claimant, and the court granted the Government a summary judgment providing for destruction of the articles. (41)

Amphetamine-containing tablets and capsules, at Philadelphia, E. Dist. Pa.

- Charged 9-14-65: while held by Russell Robinson, Philadelphia, Pa., the labeling lacked adequate directions for use, and the articles were not exempt therefrom, since the articles were in the possession of a person who was not an authorized dealer, and were not to be dispensed upon prescription; 502(f)(1). Default decree authorized release to FDA for official purposes and subsequent destruction. (42)
- George's Compound herb medicine, and components**, at Denver, Dist. Colo.
Charged 4-28-66: while held by Alpha Omega Medicine Co., Inc., Denver, Colo., the label of the medicine, which was manufactured by the dealer from components shipped in interstate commerce, and the articles' accompanying testimonials and newspaper clippings contained false and misleading therapeutic claims; and the label of the medicine lacked the name and place of business of the manufacturer, packer, or distributor; 502(a), 502(b). Consent decree ordered destruction. (43)
- Germicidal concentrate, and organic cleanser liquid**, at Minneapolis, Dist. Minn.
Charged 5-19-66: while held by Olive J. Fenney, Minneapolis, Minn., the articles' labeling, some of which had been prepared by the dealer, lacked adequate directions for use for various intended therapeutic uses; the labeling of the germicidal concentrate lacked adequate warnings against its misuse; and the labeling of the organic cleanser liquid lacked the established name of each active ingredient; 502(f)(1), 502(f)(2), 502(e)(1) (A)(i). The articles were claimed by Shaklee Products, Inc., Hayward, Calif. Pursuant to stipulation the case was removed to S. Dist. Calif. Thereafter, the claim was withdrawn and the court entered a default decree ordering destruction. (44)
- Laxative tablets**, at Newport, E. Dist. Ky.
Charged 5-26-66: while held by Harold W. Eifert, t/a L. W. Schmidt Medicine Co., Newport, Ky., the accompanying labeling, for use by the dealer in packing the bulk article into retail packages, contained false and misleading appendicitis, piles, and ulcers claims, and lacked adequate warnings against the article's misuse; 502(a), 502(f)(2). Default decree ordered destruction. (45)
- Meprobamate tablets**, 2 seizure actions at Los Angeles, S. Dist. Calif.
Charged 5-6-66 and 7-20-66: when shipped by Hallmark Laboratories, Chicago, Ill., the article, labeled in part "Meprobamate Tablets U.S.P. [or "NFI"] . . . Riverton Laboratories, Inc., Newark 8, New Jersey," was a new drug without an effective approved New Drug Application, and conditions of the article's manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice; 505(a), 501(a)(2)(B). Default decrees ordered destruction. (46)
- Pentaerythritol tetranitrate T.D. capsules and chorionic gonadotropin combination injectable and diluent**, at Indianapolis, S. Dist. Ind.
Charged 12-29-64: when shipped, the capsules from Shaw Pharmacal Co., St. Louis, Mo., and the injectable and diluent from Maizel Labs., Inc., Chicago, Ill., were new drugs without effective approved New Drug Applications; 505(a). Custom Line Laboratories, Indianapolis, Ind., claimed the articles. The claimant failed to answer interrogatories and failed to appear for a pretrial conference. Upon motion of the Government, a default decree ordered destruction of the articles. (47)
- Prednesol Plus prednisolone capsules and vials**, at Long Island City, E. Dist. N. Y.
Charged 2-8-65: while held by Parkell Products, Inc., Long Island City, N. Y., the labeling failed to bear adequate directions for use and the article, which was promoted by the dealer as a dental anti-inflammatory agent, was not exempt from such requirement, since it was a new drug and its labeling was not that authorized by an effective New Drug Application; 502(f)(1). Consent decree authorized release to the dealer for relabeling. Thereafter, the dealer, having abandoned the terms of the consent decree and having made the article available for destruction, the court ordered destruction of the article. (48)
- Prednisolone (Masteller) Desensitizing solution, prednisolone U.S.P. component and desensitizing component**, at Lake Jackson, S. Dist. Tex.
Charged 11-23-65: while held by Pharmadent Co., Lake Jackson, Tex., the labeling of the components lacked adequate directions for use, and the articles were not exempt therefrom, since they were intended by the dealer for a use in manufacture, processing, and repacking, which causes the finished article, the solution, to be a new drug for which there was no effective approved New Drug Application; and the labeling of the solution lacked adequate directions for use and it was not exempt therefrom, since it was a prescription drug which was a new drug and its labeling was not that authorized by an approved New Drug Application; 502(f)(1). Default decree ordered destruction. (49)
- Prednisolone tablets, U.S.P.**, at Baltimore, Dist. Md.
Charged 3-22-65: while held by and after being repacked by Carroll Chemical Corp., Baltimore, Md., the article's strength was deficient, and the label was false and misleading, since it lacked prednisolone (approx. 20 percent); 501(b), 502(a). The article was claimed by Davis-Edwards Pharmacal Corp., New York, N. Y. After receipt of a letter from the president of the claimant corporation, and upon motion of the Government, summary judgment was entered and the article was ordered destroyed. (50)
- Quinidine sulfate tablets, U.S.P.**, at Encino, S. Dist. Calif.
Charged 8-4-66: while held for sale, the article's quality and purity were deficient, and the labeling was false and misleading as to identity, since niacin tablets had been substituted in part for the article; 501(b), 502(a), 501(d)(2). Default decree ordered destruction. (51)
- Slender-X phenylpropanolamine hydrochloride tablets**, at Chattanooga, E. Dist. Tenn.
Charged 4-21-66: while held at Chattanooga, Tenn., by Progressive Drugs of America, Inc., and by Old Hickory Medicine Co., which had packed some of the article for Progressive Drugs, the labeling contained false and misleading claims for use as an appetite depressant in the treatment of obesity; 502(a). Consent decree ordered destruction. (52)
- Vagacreme sulfanilamide and allantoin combination**, at Jacksonville, M. Dist. Fla.
Charged 5-13-66: when shipped by E. W. Heun Co., St. Louis, Mo., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (53)

DRUGS / Veterinary

- Antibiotic for day-old chicks**, 2 seizures, at Tenaha and Nacogdoches, and at San Augustine, E. Dist. Tex.

Charged 2-11-66 and 2-14-66: when shipped by Agrisearch Laboratories, Inc., Carrollton, Ga., the article was unlabeled, and lacked an antibiotic certificate or release; 502(b)(1) & (2), 502(e)(1)(A)(i), 502(f)(1), 502(l). Default decree ordered destruction. (54)

Antibiotic mastitis combination for cows, at Ipswich, Dist. Mass.

Charged 12-19-66: while held for sale, there was no effective antibiotic certificate for the article, since certification had been revoked; 502(l)(2). Default decree ordered destruction. (55)

Bovamycin antibiotic syringes, at Indianapolis, S. Dist. Ind.

Charged 11-12-65: when shipped by Delta Laboratories, Inglewood, Calif., the strength of the article, labeled in part "Bovamycin . . . Supplied by Pitman-Moore Company Division of The Dow Chemical Company, Indianapolis," was deficient and its labeling false and misleading as to content, due to a dihydrostreptomycin deficiency (approx. 56 percent) and a neomycin deficiency (approx. 42 percent), and the article lacked an effective antibiotic certificate or release; 501(c), 502(a), 502(l)(2). Default decree ordered destruction. (56)

MEDICAL DEVICES

Aer-O-Matic electric bath aerator, at New Castle, S. Dist. Ind.

Charged 5-13-66: when shipped by Aero Home Products, Inc., Chicago, Ill., the article's name "Aer-O-Matic Home Whirlpool Unit" was false and misleading, since the article was not a bona fide whirlpool bath, and its accompanying leaflets and placards contained false and misleading therapeutic claims; 502(a). Consent decree authorized release to shipper for relabeling. (57)

Electronic muscle stimulators, at Wichita, Dist. Kans.

Charged on or about 6-16-66: while held by Figurecontrol of Kansas, Wichita, Kans., the accompanying labeling and the name "Figure-Tone" contained false and misleading figure-toning, weight-reduction, and other therapeutic claims, and the labeling lacked adequate directions for arthritis, wrinkle removal, bust development, and other therapeutic uses for which the article was offered by Doris Hawkins, a dealer sales representative; 502(a), 502(f)(1). Default decree ordered the release of two devices to FDA and destruction of the remaining devices. (58)

Electronic sine-wave generator, at Kansas City, W. Dist. Mo.

Charged 7-5-66: while held by NuArt Beauty Shoppe, Kansas City, Mo., the article's labeling lacked adequate directions for its intended use for bust development, and such directions cannot be written for such use; 502(f)(1). Default decree ordered destruction. (59)

Figurecare, Figuretron and Isotron electronic muscle stimulators, at Wichita, Dist. Kans.

Charged on or about 6-20-66: when shipped from Dallas, Tex., by Electronic Products Co., Electronic Exercise Corp., National Electronics, Charles Cranford, and/or Electronic Exerciser Corp., and while held by Figuretron, Inc., Wichita, Kans., the articles' accompanying promotional material contained false and misleading weight-reduction and other therapeutic claims, and the labeling lacked adequate directions for use for the therapeutic purposes for which the devices were offered by Jack Chism, dealer field consultant; 502(a), 502(f)(1). Default decree authorized six devices released to FDA, and remainder destroyed. (60)

Gumbrush toothbrush kit, at Shamokin, M. Dist. Pa.

Charged 2-12-65: while held by Dr. Eugene J. Knox, t/a Knox Gumbrush Co., Shamokin, Pa., the dealer's kit label and the accompanying promotional leaflets and display cards contained false and misleading therapeutic claims; 502(a). The article was claimed by the dealer. In granting the Government's motion for summary judgment and ordering destruction, the court said: that the literature, which described the claimant and his product as the "conqueror" or "preventive conqueror" of gum disease, pyorrhea, and trenchmouth, clearly indicated that "gum-brushing" would prevent and overcome those diseases; that the use and reliance on the brushes by individuals to prevent and overcome those diseases would constitute a hazard to the health of the user, since such use and reliance could prevent or delay effective means of prevention and treatment which, in turn, could lead to serious injury; and that extravagant claims for an ordinary toothbrush, called by claimant a "gumbrush," should not be permitted to contribute to these results. The court also stated that it was not necessary to consider whether or not the claims for cancer, heart disease, defective birth of offspring and loss of teeth were false and misleading since, for the Government to prevail, it was not necessary that all representations in the labeling be false, when if any single claim in the labeling is false and misleading the device is misbranded under 502(a); 231 F. Supp. 236 (1964).

The court of appeals affirmed the judgment and order of the district court and said: that, although the claimant, a nonmember of the bar, conducted the case on behalf of the seized articles himself, the proceedings in the lower court were conducted properly in the light of *One 1958 Plymouth Sedan v. Com. of Pennsylvania*, 380 U.S. 693 (1965); and that forfeiture proceedings under the Food, Drug, and Cosmetic Act are independent of a criminal proceeding and may be effected without regard to any person's criminal responsibility under the penalty provisions of the Act; 352 F.2d 344 (C.A. 3, 1965); cert. denied 383 U.S. 913 (1965). (61)

Isotron electronic muscle stimulator, at Concord, N. Dist. Calif.

Charged 6-24-66: when shipped by Electronic Products Co., Dallas, Tex., and while held by Figure-tone of Oakland, Concord, Calif., the accompanying promotional material contained false and misleading weight-reduction and other therapeutic claims, and the labeling lacked adequate directions for use for the therapeutic purposes for which the device was offered by Carol Meek and/or Jayne Carscadden, dealer sales representatives; 502(a), 502(f)(1). Default decree authorized release to FDA. (62)

Kontoural brassieres, at Aurora, Geneva, and Batavia, N. Dist. Ill.

Charged 7-11-66: when shipped by Gretzinger Associates, Pasadena, Calif., and while held for sale, the accompanying promotional material contained false and misleading bust-development, cancer-prevention, and other therapeutic claims; and the labeling of the article lacked adequate directions for the therapeutic uses for which the article was offered by Lois Eissner, a distributor for John W. Arnold & Associates, Batavia, Ill.; 502(a), 502(f)(1). Default decree authorized donation to public/charitable institution and/or destruction. (63)

McKune Whirlpool bath aerator, at Ogdensburg, N. Dist. N.Y.

Charged 11-4-65: when shipped by John J. McKune & Sons Co., Inc., Chicago, Ill., the name "Whirlpool Bath" and therapeutic claims in the

accompanying promotional material were false and misleading; 502(a). Default decree ordered destruction. (64)

Relax-O-Bath electric bath aerator, at River Falls and Hudson, W. Dist. Wis. Charged 6-23-66: when shipped by Vimco Sales, Minneapolis, Minn., and while held for sale, the accompanying promotional material contained false and misleading arthritis, tension, varicose veins, insomnia, and other therapeutic claims; 502(a). Consent decree authorized release to shipper for relabeling. (65)

Vibro Jet electric bath aerator, at Lincolnwood, N. Dist. Ill.

Charged 5-4-66: when shipped by Versa Tool Manufacturing Co., Inc., Racine, Wis., and while held by Telmark, Inc., Lincolnwood, Ill., the device's name "Whirlpool Bath" was false and misleading, since the article was not a bona fide whirlpool bath device, and the dealer's accompanying promotional material contained false and misleading therapeutic claims; 502(a). Consent decree authorized release to dealer for relabeling. (66)

HAZARDOUS SUBSTANCES

Catalyst, at Seattle, W. Dist. Wash.

Charged on or about 12-30-66: while held for sale, the article was a corrosive substance containing methyl ethyl ketone peroxide, and its containers lacked a number of the required conspicuous label statements; 2(p)(1)(C,E,F,G & J). Default decree ordered destruction. (67)

Cracker Ball ball-type explosive caps, 30 seizure actions at Baton Rouge, E. Dist. La., Renick, E. Dist. Mo., Kearney, Dist. Nebr., Affton, E. Dist. Mo., Fort Smith, W. Dist. Ark., Sioux Falls, Dist. S. Dak., Fort Dodge, N. Dist. Iowa, Birmingham, N. Dist. Ala., Baltimore, Dist. Md., Brooklyn, E. Dist. N. Y., Mandan, Dist. N. Dak., Ekland, M. Dist. Pa., Niles, W. Dist. Mich., Anchorage, Dist. Alaska, Eugene, Dist. Ore. (2 seizures), Clover, W. Dist. S. C., West Monroe, W. Dist. La., Pittsburgh, W. Dist. Pa., Leesburg, M. Dist. Fla., San Ysidro, S. Dist. Calif., Denver, Dist. Colo., Spartanburg, W. Dist. S. C., Hilo, Dist. Hawaii (2 seizures), Burlington, Dist. Vt., Haverhill, Dist. N. H., Cynthia, E. Dist. Ky. (2 seizures), and Providence, Dist. R. I. Charged between 6-15-65 and 12-1-65: when shipped by Iwakami Co., Yokohama, Japan, Maison Albert David, Taipei, Taiwan, Sanyu Co., Ltd., Shizuoka, Japan, Ikenbunfireworks Co. Yaizu City, Japan, Nan Sin Hang Fireworks, Taiwan, Pao Sheng Hong, Tainan, Taiwan, Onda Enterprises, Ltd., Daito-Ku, Tokyo, Japan, and unknown shippers in Japan and Taiwan, the articles were extremely flammable solid substances that generated pressure through explosion when subjected to friction or to percussions, and their containers lacked required conspicuous label statements; 2(p)(1)(A, C, E, F, I & J). Consent decrees in the actions in Dist. S. Dak., Dist. Md., E. Dist. N. Y., Dist. Vt., and E. Dist. La., ordered destruction. Default decrees in the other actions ordered destruction. (68)

Novelty kits containing miniature blank cartridges and a tieclasp or keyring pistol, at Atlantic City, Dist. N.J.

Charged 1-30-67: when shipped by Silvercraft Co., Inc., Boston, Mass., the articles generated pressure and exploded when subjected to percussion, and the kits lacked required conspicuous label statements and were not exempt therefrom; 2(n)(1)(A, B, D & J). Consent decree authorized release to shipper for relabeling. (69)

Wood reconditioner and sealer, at St. Louis, E. Dist. Mo.

Charged 2-17-67: while held for sale, the article was a toxic substance presenting a special hazard because of its petroleum distillate content (approx. 10 percent), and its containers lacked a number of the required conspicuous label statements; 2(p)(1)(B,F & J), 3(b). Default decree ordered destruction. (70)

**NOTICES OF JUDGMENT on Criminal Cases
FOOD**

Campbell Grocery Co., Inc., Mobile, S. Dist. Ala.

Charged 3-20-67: flour, sugar, and hominy grits were held in a building accessible to rodents, and were contaminated with rodent filth; 402(a)(4), 402(a)(3). Guilty plea; fine. (71)

Choice Baking Co., Div. of Norris Dairy Products Co., Stanley Norris, Don F. McGraw, and Ernest Ebell, Comanche, N. Dist. Tex.

Charged 4-3-67: when shipped, cookies, labeled in part "Mrs. Alison's Cookies Fudgies [or "Peanut Butter" or "Lemon Cremes"] Mrs. Alison's Cookie Co. Overland, Mo.," contained insect and rodent filth, and had been prepared and packed under insanitary conditions—402(a)(3), 402(a)(4); and oatmeal was held in a building accessible to rodents, and was contaminated with rodent filth; 402(a)(4), 402(a)(3). Nolo contendere plea by corporation; fine. Nolo contendere plea by individuals; probation. (72)

Ellis Pecan Co., Inc., and Jackie C. Ellis, president, Fort Worth, N. Dist. Tex. Charged 5-5-67: when shipped, shelled pecans contained bacterial filth and *E. coli*, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Guilty plea by individual; imprisonment suspended, and probation. (73)

Florida Maid Foods, Inc., Jacksonville, M. Dist. Fla.

Charged 12-12-66: cornmeal was held in a building accessible to rodents, and was contaminated with rodent filth; 402(a)(4), 402(a)(3). Nolo contendere plea; fine. (74)

J. B. Kramer Grocery Co., Inc., Batesville, E. Dist. Ark.

Charged 10-11-66: pancake mix, cornmeal, and flour were held in a building accessible to insects and rodents, and were contaminated with insect and rodent filth; 402(a)(4), 402(a)(3). Guilty plea; fine. (75)

D. McCrea & Son, Inc., Daniel M. McCrea, president, and **Auda V. McCrea**, vice president, Yancey, W. Dist. Tex.

Charged 11-14-66 by grand jury: when shipped, shelled pecans, labeled in part "Fiesta Brand Fancy Shelled Pecans Packed by D. McCrea & Son, Inc. . . . Gilbert Nut House . . . L. A. Calif.," contained *E. coli*, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Guilty pleas by individuals; imprisonments and probations. (76)

Parker's Products, Inc., Barney B. Parker, president, and **Lyle B. Pattie**, plant manager, Fort Worth, N. Dist. Tex.

Charged 7-8-66: when shipped, candy, labeled in part "Pangburn's Candy Ice Cream Flavors Lemon Flake [or "Candy Cane"] Distributed by Parker's Products, Inc.," contained insect and rodent filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4).

Nolo contendere pleas by the corporation and Parker; fines. Not guilty plea by Pattie. After trial by the court, Pattie found guilty and fined. (77)

Robinson Public Warehouse Co., and Arthur G. Robinson, president, Houston, S. Dist. Tex.
Charged 2-27-67 by grand jury: rice pudding, pizza, noodle, and egg foo yong mixes were stored in a building infested with insects, and were contaminated with insect filth; 402(a)(4), (402(a)(3). Nolo contendere pleas; fines. (78)

Rock Creek Ginger Ale Co., Inc., Washington, Dist. Columbia.
Charged 5-3-66: when manufactured within the District, and when shipped, a dietary beverage labeled in part "Trim diet Cola . . . 1/6 Calorie Per Fl. Oz. . . . Trim Beverages Inc., Washington, D.C." had a beverage containing approximately 13 percent sugar and an orange flavor substituted for the article; 402(b)(2). Nolo contendere plea; fine suspended. (79)

Shedd-Bartush Foods, Inc., Brantley D. Tew, branch manager, William Guy Cloer, plant superintendent, Greenville, Dist. S. C.
Charged 3-15-67: when shipped, margarine, labeled in part "Select Foods Margarine Packed for Select Foods, Inc., Hendersonville, N. C." and "Oleomargarine Shedd-Bartush Foods, Inc., General Offices, Detroit 38, Michigan," had been prepared and packed under insanitary conditions; 402(a)(4). Guilty plea by corporation; fine. Guilty pleas by individuals; fines suspended and probation. (80)

Tagus Wholesale Grocery Corp., and Joseph Alcobia, New Bedford, Dist. Mass.
Charged 3-29-67: fava beans were held in a building accessible to rodents, and were contaminated with rodent filth; 402(a)(4), 402(a)(3). Guilty plea by corporation; fine. Guilty plea by individual; probation. (81)

Trinacria Macaroni Works, Baltimore, Dist. Md.
Charged 3-21-67: macaroni was held in a building accessible to insects, and was contaminated with insect filth; 402(a)(4), 402(a)(3). Nolo contendere plea by the partnership; fine, plus costs. (82)

DRUGS

Bahne K. Bahnson, D. O., Burt N. Dist. Iowa.
Charged 2-11-66 by grand jury: secobarbital sodium capsules and amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). The court granted the defendant's motion for inspection and copying of the written or recorded statements made by the defendant in the hands of the Government, saying that the request came within Rule 16(a) of the Rules of Criminal Procedure. The court also cited *Roviano v. U.S.* 353 U.S. 53 and *Rusendorf v. U.S.* 376 U.S. 528, 534, and granted the defendant's motion for the true name and whereabouts of a person claimed to be a witness to the transactions charged, if the person did have knowledge of any facts in any way bearing on the charges in the indictment. Guilty plea; fine and probation. (83)

James L. Beatty, New York, S. Dist. N. Y.
Charged 7-20-65: when LSD was shipped from New York, N. Y., to Chicago, Ill., it was a new drug without an approved New Drug Application; and it lacked a label containing the name and place of business of the manufacturer, packer, or distributor, a statement of quantity of contents, and the established name of the drug; its labeling lacked adequate directions for use and warnings against dangerous and unsafe use; and while held for sale at Chicago after shipment from New York, LSD was caused to be dispensed without a prescription; 503(b)(1), 505(a), 502(b)(1) & (2), 502(e)(1)(A)(i), 502(f)(1) & (2). Guilty plea; imprisonment and probation. (84)

Dennis Muri Bishop, Fort Worth, N. Dist. Tex.
Charged 12-14-66 by grand jury: methamphetamine combination tablets and pentobarbital sodium capsules were unlawfully sold and delivered; 301(q)(2). Guilty plea; imprisonment. (85)

George H. Croft, Jr., St. Louis, E. Dist. Mo.
Charged 10-24-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; probation. (86)

James Graves and Jerome J. Schalk, truckdrivers, Omaha, Dist. Nebr.
Charged 4-22-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Nolo contendere plea by Graves; imprisonment and probation. Guilty plea by Schalk; probation. (87)

Johnny Jewell, Texarkana, E. Dist. Tex.
Charged 8-23-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment suspended, fine, and probation. (88)

Kiser Drug Co., Inc. No. 2, and George A. Gregory, pharmacist, Charlotte, W. Dist. N. C.
Charged 2-16-67: Preludin tablets were dispensed as unauthorized refills; 503(b)(1). Guilty pleas; fines. (89)

Oscar H. Locke, t/a 60 Grand Truck Stop, and Don Hughes, truck-stop employee, Wyandotte, N. Dist. Okla.
Charged 10-24-66: dextro-amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea by Locke; fine, probation. Guilty plea by Hughes; probation. (90)

George E. Miller, D. S. C., Camarillo, S. Dist. Calif.
Charged 11-28-66: capsules containing amphetamine sulfate were unlawfully sold and delivered; 301(q)(2). Nolo contendere plea; probation. (91)

H. Noel Nyman and Henry G. Marak, pharmacists, Bonner Springs, Dist. Kans.
Charged 6-3-66: Desbutal tablets were dispensed as unauthorized refills; 503(b)(1). Guilty pleas; imprisonments suspended, fines, plus costs, and probations. (92)

William B. Pratt, Knoxville, E. Dist. Tenn.
Charged 5-4-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Not guilty plea. After trial by court and jury, verdict of guilty; imprisonment. (93)

Cecil C. Shaw, M.D., Loxley, S. Dist. Ala.
Charged 10-3-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; fine and probation. (94)

Southern Drug & Manufacturing Co., Inc., Knoxville, E. Dist. Tenn.
Charged 5-6-65: when shipped, Nova-Sul trisulfonylpyrimidines tablets, U.S.P., failed the U.S.P. disintegration requirement—501(b); vasoconstrictor antihistaminic liquids were deficient in strength, quality, and purity, since they lacked chlorpheniramine maleate; and products containing pheniramine maleate and no chlorpheniramine maleate had been substituted for such liquids—501(c), 501(d)(2); and butabarbital sodium elixir, N.F., was deficient in quality, since the article contained unpermitted color and flavor and lacked alcohol and saccharin sodium. Guilty plea; fine. (95)

Earl Teague, truck-stop operator, and **William Lee McGonigal**, truck-stop employee, Texarkana, E. Dist. Tex.
Charged 2-7-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea by Teague; imprisonment suspended, fine, and probation. Guilty plea by McGonigal; imprisonment suspended and probation. (96)

Rowell Wilson of McColl, S.C., George Russell Batchelor of Bennettsville, S.C., William Howell of Society Hill, S.C., and Harold J. Flowers of Darlington, S.C., E. Dist. S.C.
Charged 10-1-64: amphetamine tablets were dispensed without a prescription; 503(b)(1). Guilty pleas; imprisonments suspended and probations. (97)

Carl Wright, truck-stop operator, and **David C. Rice, Derwood Everett, and Bob Spence**, employees, 2 criminal actions, Sealy, S. Dist. Tex.
Charged 1-25-66 (all defendants except Spence): amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Not guilty pleas.
Charged 3-7-66 by grand jury: conspiracy to dispense prescription-type drugs without a prescription; 18 U.S.C. 371, 503(b)(1). Not guilty pleas.
The actions were tried together. After trial by jury, guilty verdicts were returned; imprisonments and probations. (98)

INJUNCTION ACTIONS

Bolar Pharmaceutical Co., Inc., Robert Schulman, president, and **Lawrence R. Raisfeld**, secretary-treasurer, Brooklyn, E. Dist. N. Y.
Charged 6-20-63 in a complaint for injunction: that the defendants were engaged in the business of manufacturing, packing, labeling, selling, and distributing in interstate commerce, various drugs which were adulterated and/or misbranded as follows: (a) their strengths differed from and their quality fell below U.S.P. and N.F. standards, (b) their labeling was false and misleading with respect to the quantity of their components, (c) their labels lacked an accurate statement of quantity of contents, (d) their labeling lacked adequate warnings against misuse, and (e) they were prescription drugs and lacked the prescription legend; 501(b), 502(a), 502(b)(2), 502(f)(2), 503(b)(4); that the violative conditions of the drugs resulted from deficiencies and inadequacies in the methods used in, and the facilities and controls used for the manufacture, packing, and labeling of the drugs, and that the defendants were well aware of the violative nature of their acts.

A temporary restraining order and a consent decree of permanent injunction enjoined the shipment of drugs which were adulterated and misbranded as charged, enjoined the shipment of any drugs in interstate commerce unless a number of specified facilities, methods, and controls were used by the defendants for the manufacture, processing, and packing of drugs; and ordered the destruction of finished drug products in stock manufactured before the complaint was filed, and required the labels of drugs manufactured after that day to be satisfactory and the defendants to present satisfactory evidence that the drugs had been properly assayed. (99)

Hampton Manufacturing Co., Inc., Sanette Manufacturing Co., Inc., C. I. Lee Co., Inc., Clarence I. Lee, president, and **Nicholas G. Dales**, vice president, New Rochelle, S. Dist. N. Y.
Charged on or about 12-6-66 in complaint for injunction: that the defendants were shipping in interstate commerce "Blue Cross" and "Sanette" brand Adhesive Bandages, U.S.P., which were purported to be sterile, when significant numbers of these adhesive bandages were found to be contaminated with living micro-organisms, and that sterilization procedures and controls were inadequate in that: (1) sterility tests were not performed before the adhesive bandages were distributed; (2) persons with sufficient competence to assure proper sterility tests and procedures were not employed; (3) the ethylene oxide sterilization process was improperly administered and no records of such process were kept; (4) the adhesive bandages in the ethylene oxide sterilization unit were improperly packed; and (5) indicator and spore strips which were used to test the efficacy of the sterilization process were improperly placed at the top of the sterilization load and were improperly processed and interpreted after removal from the load; 501(a)(2)(B), 501(b), 502(a).

Consent decree enjoined: the violative acts complained of; the shipping of any of the inventory of adhesive bandages manufactured before the institution of good manufacturing practice sterilization procedures, unless such adhesive bandages were destroyed or sterilized; and the shipping of adhesive bandages which were not manufactured under good manufacturing practice and sterilization procedures, and did not have the sterility level set forth in the U.S.P., or had labeling which was false and misleading in regard to the sterility of the adhesive bandages. (100)

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

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

James L. Goddard, Commissioner of Food and Drugs
Washington, D.C., November 1, 1967

FDA PAPERS

In its second year
FDA PAPERS will continue to express agency concerns
for the benefit of business decisionmakers,
to explain the problems and challenges facing administrative and
scientific managers, and to inform all of the activities and actions of the
Food and Drug Administration.

ARTICLES WILL ANSWER QUESTIONS LIKE:

- "What is FDA's view of the future for drug promotion?"
- "How does FDA relate to FTC, USDA, and other Federal Agencies?"
- "What is the problem with Staph?"
- "What's new in drug abuse control?"
- "Can we expect another FDA reorganization?"
- "What happened to the dietary food regulations?"
- "How does a modern FDA District operate?"
- "Is there more to be done to protect children?"
- "Does FDA have a role in physician education?"
- "What is the FDA drug compendium?"

AND—MORE FULL COLOR!

MAIL ORDER FORM

Mail to Government Printing Office
Superintendent of Documents
Washington, D. C. 20402

FOR USE OF SUPT. DOCS.	

Enclosed find \$_____ (check, money order, or Supt. of Documents coupons). Please enter
my subscription for FDA PAPERS at \$5.50 a year. (\$1.25 additional for foreign mailing.)

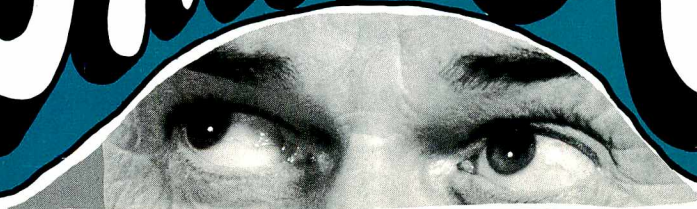
Name _____

Address _____

City, State, Zip Code _____

LOOK WHAT'S

COMING UP



OFFICIAL BUSINESS

Announcements

FDLI-FDA CONFERENCE SPEAKERS

Dr. Douglas G. Chapman, Assistant Director General of the Canadian Food and Drug Directorate, will be the banquet speaker of the FDLI-FDA conference on November 27. "A Neighbor Looks at the U.S. Food and Drug Laws" will be the title of his address. Toastmaster for the windup event of the 1-day conference will be Melvin W. Allredge, chairman of the Great Atlantic and Pacific Tea Co., Inc.

The question-and-answer panel, a feature of the conference's general session in the morning, will be composed of William W. Goodrich (Assistant General Counsel, Food and Drug Division, DHEW); H. Thomas Austern (Covington & Burling); Kenneth R. Lennington (Salmonella Project Officer, FDA); Edward Brown Williams (Harter, Calhoun & Williams); J. Kenneth Kirk (Associate Commissioner for Compliance, FDA); Vincent A. Kleinfeld (Kleinfeld & Kaplan); and Dr. John M. Newton (Standard Brands, Inc.).

Separate panel workshops on food and drugs will be the order of business during the afternoon session.

Preconference registration facilities for those arriving early, or for those who wish to avoid the rush on conference morning, will be available at the Marriott Twin Bridges Motor Hotel, Washington, D. C., from 3 to 9 p.m., Sunday, November 26. Also, a few unsold luncheon and/or reception-dinner tickets will be available at the registration desk for those who failed to mail their reservation before the deadline.

SYMPOSIUM PROCEEDINGS PUBLISHED

Proceedings of the FDA sponsored Symposium on the Safety of Large Volume Parenteral Solutions, held in July 1966, have been published. The 103-page Proceedings contain not only the highly technical scientific papers presented at the symposium but also significant portions of the discussion sessions.

Single copies of the Proceedings are available from the Bureau of Education and Voluntary Compliance, E-1, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204.

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

SCHEDULE OF FDA WORKSHOPS AND REGIONAL CONFERENCES NOVEMBER & DECEMBER 1967

FDA District or BDAC Field Office	Date	Location	Subject Area
Atlanta	November 2	Tampa, Fla.	Sanitation in Food Warehousing
	November 7	Columbia, S. C.	Medicated Feeds
Buffalo	November 2	Greensburg, Pa.	Bacteriological Problems in Convenience Foods
Chicago	November	Chicago, Ill.	Sanitation in Food Warehousing (3 1-day workshops)
Kansas City	November 15	Lincoln, Nebr.	Medicated Feeds
Los Angeles	November 15	Riverside, Calif.	Medicated Feeds
	November	Los Angeles, Calif.	GMP—Drugs
Philadelphia	November 14	Philadelphia, Pa.	Sanitation in Food Warehousing
San Francisco	November 4	Eureka, Calif.	Bacterial Contamination—Frozen Shrimp
Seattle	November 7	Newport, Oreg.	Bacterial Contamination—Frozen Shrimp
Cincinnati	December 7	Cincinnati, Ohio	Medicated Feeds
Dallas	December 5	San Antonio, Tex.	Sanitation in Food Warehousing
Detroit	December 5	Detroit, Mich.	Medicated Feeds
New Orleans	December 12	Birmingham, Ala.	Pesticide and Drug Residues in Eggs and Poultry Products
Philadelphia	December 5	Trenton, N.J.	Medicated Feeds
Seattle	December	Seattle, Wash.	Pesticide Analytical Methods