

MAY 1970

# **FDA PAPERS**

## **ORAL CONTRACEPTIVES**

**A Status Report**

## **BACTERIA IN COSMETICS**

**A Medical Evaluation**

## **MAJOR FDA UNITS AND THEIR FUNCTIONS**

## **DISTRICT REALIGNMENT**

**Advisors to Help Upgrade  
FDA's Scientific Standing**







*"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

**T**he Commissioner of Food and Drugs has appointed an internal Science Advisory Committee (see page 21) to focus the Agency's best scientific thought on the issues requiring action and to assure agencywide coordination in this task.

His further appointment of a group of distinguished outside experts, the Ritts Committee, to review and evaluate the Agency's entire scientific effort and advise him on all science activities (see page 15) is, whatever else it may be, a frank acknowledgment that neither he nor the Agency is omniscient in the sciences involved in FDA's regulatory work.

Is anyone?

Yet, under the law, he has been delegated the unenviable responsibility of acting almost daily on issues that hold the utmost significance for public health. His decisions must be on the soundest scientific ground. The public is entitled to this kind of protection under the law.

The Ritts Committee will be a safeguard to assure that the Agency's total scientific effort is in tune with that of the most advanced thinkers of the scientific community.

# quotes

"It is to be noted that if a hospital engages in drug manufacturing to supply not only its own needs but those of other institutions, its operation may fall outside of what may be properly considered hospital practice and may invite application of the Federal Food, Drug, and Cosmetic Act with respect to such operations. If, however, such operations are undertaken within its own facilities to meet the hospital's own drug needs, they are recognized by FDA as normal hospital practice of dispensing drugs on prescription. Even if the latter is true, individual hospitals should use the Good Manufacturing Practice regulations as a guide to assure that they have adequate resources such as personnel, manufacturing, and control facilities to assure that the drugs which they manufacture, repackage, or relabel meet the standards of integrity. We would hope that the bulk of such practices would be subject to such self-regulation to make Government regulatory activity unnecessary."

*Theodore E. Byers, Director, Office of Compliance, Bureau of Drugs, at the Unit Packaging of Pharmaceuticals Seminar, Saint Louis, Missouri, May 18, 1970.*

"About two weeks ago a contract was signed with the National Academy of Sciences to develop a questionnaire for the manufacturers and formulators making or using substances now on the GRAS list, and to field test this questionnaire. Hopefully this job will be complete about six months from now. . . .

"The advantages of the Academy survey are many. First it takes the job out of the pressure cooker—it should be free of the pulling and tugging of regulatory responsibilities. Secondly, it will enhance the probability of accurate reporting of the extent and volume of usage—thanks to the fine cooperation of the Industry Liaison Panel of the Food Protection Committee. Finally, among other things, it does not constitute an additional effort to be made by an already overworked FDA staff, but will be done by an experienced and proven team. By the time the final evaluation of findings is made we will have worked out an orderly procedure for accomplishing that."

*Dale R. Lindsay, Associate Commissioner for Science, at the 61st Annual Convention of the Flavor and Extract Manufacturers Association, Boca Raton, Florida, May 4, 1970.*

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Secretary, U.S. Department of Health, Education, and Welfare

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

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

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

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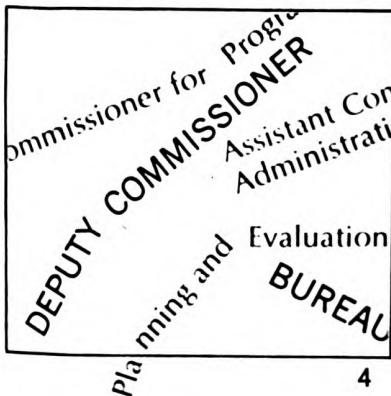
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# FDA PAPERS

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## FDA Units and Their Functions

For the convenience of readers, FDA PAPERS herewith presents a condensed version of the Statement of Organization, Functions, and Delegations of Authority which was effective February 1 and implements the order signed January 5 by the Secretary of Health, Education, and Welfare reorganizing the FDA.

The Statement defines the functions and responsibilities of the major FDA units under the new organizational setup. The complete Statement published in the *Federal Register* of February 25 (and available from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402) defines these functions down through the division level.

Shortly after the reorganization, in late February and early March, all of FDA's headquarters offices in the Washington area, except for the new Bureau of Foods, Pesticides, and Product Safety, and one major unit

of the Bureau of Drugs, were physically relocated to the following address: 5600 Fishers Lane, Rockville, Maryland 20852. The mailing address for the Bureau of Foods and for the Office of Pharmaceutical Sciences, Bureau of Drugs, remains as follows: 200 C Street, S.W., Washington, D.C. 20204.

### AGENCY MISSION

FDA's mission is to protect the public health from impairment by foods, drugs, cosmetics, therapeutic devices, hazardous household substances, poisons, pesticides, food additives, flammable fabrics, and various other types of consumer products. Its regulatory functions are intended to insure that foods are safe, pure, and wholesome; drugs and therapeutic devices are safe and effective; cosmetics are harmless; all of these are honestly and informatively labeled and packaged; dangerous household products carry adequate warnings



for safe use and carry proper labeling; drugs are not counterfeited; and hazards from use of various consumer products are minimized.

### OFFICE OF THE COMMISSIONER

The Commissioner and Deputy Commissioner are responsible for efficiently and effectively carrying out FDA's mission under direction of the Assistant Secretary for Health and Scientific Affairs.

Operating in the Office of the Commissioner as principal advisors to him in implementing agency policy in their areas of cognizance are the following two offices:

### ASSOCIATE COMMISSIONERS—

**For Compliance:** Acts as principal advisor in regulatory and compliance matters that affect policy and direction and long-range goals; coordinates overall compliance effort to assure best use of FDA resources, a balance between voluntary and regulatory compliance, and responsiveness to consumer needs; keeps the Agency alert to the need for promptly obtaining compliance by the regulated industries; directs rulemaking activities and *Federal Register* entries; operates the Emergency Preparedness and Civil Defense Program; keeps in contact with other nations, foreign firms, and international groups on compliance matters.

**For Science:** Acts as principal advisor in scientific matters that affect FDA policy and directions and long-range goals; gives leadership in promoting agency scientific matters and scientific and technological achievement; heads an internal Science Advisory Committee of representatives from the bureaus whose members advise on scientific policy and coordination of scientific activities; leads in development, application, and evaluation of research, training, and fellowship grant activities; coordinates scientific relationships with international groups and other countries and the preparation of international travel plans; maintains continuing appraisal of agency scientific programs including contracted research; is responsible for FDA committee management; directs the agency safety program.

Operating in the Office of the Commissioner are the following two offices:

**Hearing Examiner:** Sets and conducts prehearing conferences and administrative hearings of both adjudicative and rulemaking nature under applicable laws; evaluates evidence on the record after hearings and prepares the necessary reports, tentative findings of fact, conclusions of law, and tentative orders for use by the Commissioner in making final agency decisions.

**Legislative Services:** Advises the Commissioner about legislative needs and assists in analyzing pending legislation in Congress of importance to FDA; helps prepare agency position papers and DHEW reports on proposed legislation for the Commissioner; coordinates and assists in development of FDA legislative proposals for the Commissioner's review; helps prepare FDA testimony before congressional committees and monitors congressional activities; helps obtain information requested

by congressional committees and furnishes assistance to Congressmen or congressional committees; monitors and manages correspondence involving the White House, Congress, State and local officials, and other countries.

Operating directly under the Office of the Commissioner and keeping him advised on matters in their respective areas, these offices generally assist in developing and carrying out agency plans and policy in their respective areas of cognizance:

### ASSISTANT COMMISSIONERS—

**For Administration:** Acts as principal advisor on FDA management operations; assumes responsibility for effective use of management of resources and implementation of operating programs by coordinating the Agency's funding, manpower, facilities, and equipment needs; directs administrative management, including budget, finance, personnel, organization, management information methods, procurement and property, records, and similar supporting activities.

Divisions: Financial Management, General Services, Management Systems, and Personnel Management.

**For Planning and Evaluation:** Advises and assists in long-range program planning, development, and evaluation; develops program and planning strategy; develops the Five-Year Plan in the Planning-Programming-Budgeting System; develops two-year operational objectives to support long-range plans; conducts operations research and special studies to forecast trends, needs, and major problems; evaluates agency accomplishments against objectives and priorities; evaluates the impact of agency programs on consumer protection.

**For Field Coordination:** Oversees FDA Regions and Districts, advising and assisting in development and execution of policies and operational guidelines for management of Regional and District activities and issuance of proposals and instructions; directs and counsels office management; assesses and acts to improve management of Regional and District activities; serves as headquarters contact for coordinated field support services; evaluates the performance and capabilities of staffs and helps formulate career development plans; provides for coordination among the Regions and Districts and with headquarters; recommends, coordinates, and provides staff assistance for joint program planning activities between FDA and State and local agencies.

**For Program Coordination:** Directs efforts toward early identification of potential and emerging major problems, takes or recommends preventive or remedial measures against them, and follows through as necessary; reviews and coordinates review by other agency officials of major issues and studies affecting policies, directions, organization, and functions; develops policy on and ways to maintain integrity of trade secrets and other information submitted to FDA by industry on a confidential basis; formulates policy on and recommends action on security problems; provides central computer

operations and programming services and technical guidance on new ADP techniques and equipment, and develops systems policy; provides advice and coordination for developing and operating an integrated science information system.

**For Education and Information:** Disseminates education and information about FDA's mission to the public and the regulated industries; conducts a public information program intended to create a positive atmosphere for agency regulatory activities and to promote recruitment; acts as focal point for dissemination of news about agency activities; carries on a consumer education program; maintains a liaison program with the medical profession to promote understanding of and support for agency activities; conducts and arranges for training and educational programs related to agency activities for Federal, State, and local personnel; provides editorial, design, and graphic arts services; answers public inquiries on matters of consumer interest.

### **BUREAU OF FOODS, PESTICIDES, AND PRODUCT SAFETY**

Conducts research and develops standards and policy on the composition, quality, nutrition, and safety of foods, food additives, colors, cosmetics, pesticides, and other potentially harmful products; conducts research to improve the detection, prevention, and control of harmful contamination; oversees surveillance and compliance programs in foods, pesticides, and product safety; reviews industry petitions and recommends regulations on food standards and on safe use of color and food additives and pesticides; provides scientific and technical support in food chemistry, toxicology, nutrition, microbiology, sanitation control, pesticides, and product safety; analyzes regulatory samples as necessary to support compliance programs.

#### **Offices**

**Of Foods and Nutritional Sciences:** Develops scientific standards and conducts research on food composition, quality, nutrition, and safety; reviews industry petitions and recommends regulations for food standards and safe use of color and food additives; analyzes samples necessary to support compliance programs.

**Divisions:** Food Chemistry and Technology, Nutrition, Microbiology, Toxicology, Pathology, and Colors and Cosmetics.

**Of Pesticides and Product Safety:** Carries out programs to reduce injuries, morbidity, and mortality from accidents with consumer products; conducts epidemiological studies of pesticides and their effects on man; develops scientific standards on and researches composition, quality, and safety of pesticides; reviews industry pesticide petitions and pesticide registration applications and recommends regulations and labeling to reduce potential health hazards; provides advice and guidance on hazards of household products and precautionary labeling.

**Divisions:** Pesticide Chemistry and Toxicology, Pesti-

cide Community Studies, Poison Control, Hazardous Substances, Product Safety Studies, and Product Research.

**Of Compliance (FPPS):** Advises the Bureau Director and other officials on the law, regulations, legal administrative and regulatory problems, and administrative policies concerning regulatory responsibilities relating to food, pesticides, and product safety; develops compliance and surveillance programs covering industries in food, pesticides, and product safety; fosters development of good manufacturing practices and improved food sanitation; develops regulations, model codes, and other standards for industry practices and control of health hazards associated with food, including shellfish and milk, and interstate travel; conducts programs for voluntary compliance by industry; helps public and public service institutions and agencies with technical ways to control health hazards in interstate shipment of food, including shellfish and milk, and interstate travel; on request, supports and guides District offices in handling legal actions and provides headquarters case development, coordination, and assistance in contested cases; checks on degree of industry compliance with statutes and regulations; operates a control system for all pesticide and food petitions submitted to FDA for review and evaluation.

**Divisions:** Case Guidance (FPPS), Regulations and Petitions Control, Industry Services (FPPS), Compliance Programs (FPPS), and Sanitation Control.

### **BUREAU OF DRUGS**

Develops standards and medical policy and conducts research on efficacy, reliability, and safety of drugs and devices for man; reviews and evaluates New Drug Applications and claims for investigational drugs; conducts clinical studies on safety and efficacy of drugs and devices; operates an adverse drug reaction reporting system; oversees surveillance and compliance programs on drugs and devices; provides scientific and technical support in drug biology and drug chemistry; assumes responsibility for regulations, model codes, and other standards covering drug industry practices and fosters development of good manufacturing practices; oversees the antibiotic and insulin certification program.

#### **Offices**

**Of New Drugs:** Evaluates, for safety and efficacy, New Drug Applications (NDA's) for marketing new drugs; evaluates adequacy of proposed labeling for use and warnings against misuse; evaluates manufacturing and laboratory methods, facilities, and controls in factories producing new drugs; reviews notices of claimed investigational exemption for new drugs (IND's) and recommends action to restrict or stop further testing; reviews clinical investigators and scientific investigations of investigational new drugs and New Drug Application areas and coordinates follow-up with the Office of Compliance.

**Divisions:** Anti-Infective Drugs, Cardiopulmonary



and Renal Drugs; Dental and Surgical Adjuncts; Metabolism and Endocrine Drugs; Neuropharmacological Drugs; Oncology and Radiopharmaceuticals, and Scientific Investigations.

**Of Marketed Drugs:** Evaluates safety and efficacy data and proposed labeling in supplements to New Drug Applications; carries out continuing surveillance and medical evaluation of labeling, clinical experience, and reports required of applicants for all drugs and devices for which a new drug approval is in effect; reviews inspections and other findings to determine if new drugs are being marketed in accord with commitments in New Drug Applications; makes recommendations on withdrawal of approval of the NDA; takes final action on antibiotic and insulin samples submitted for certification and on requests for exemptions from antibiotic certification; reviews for safety, reliability, and effectiveness the new and marketed therapeutic and clinical devices and recommends action on significant hazards or potential danger from inadequacy of directions for use or warning and cautionary information; obtains and evaluates reports of adverse drug reactions.

**Divisions:** Certification Services, Clinical and Medical Devices, Drug Experience, Cardiopulmonary-Renal Drug Surveillance, Metabolic-Endocrine Drug Surveillance, Neuropharmacological Drug Surveillance, and Surgical-Dental Drug Surveillance.

**Of Compliance (Drugs):** Advises the Bureau Director and other officials on the law, regulations, legal-administrative problems, regulatory problems, and administrative policies concerning regulatory responsibilities for drugs and devices; conducts studies to determine medical policy and support regulatory action; develops compliance and surveillance programs covering regulated industries; develops or coordinates development of regulations and other standards covering industry practices and fosters development of good manufacturing practices; conducts programs to encourage voluntary compliance by industry; on request, supports and guides District offices in handling legal actions and provides headquarters case development, coordination, and assistance in contested cases; develops and coordinates studies on degree of compliance by regulated industries with statutes and regulations enforced by FDA; monitors and evaluates professional journal advertising and promotional and related labeling to determine veracity of claims.

**Divisions:** Case Guidance (Drugs), Compliance Programs (Drugs), Drug Advertising, Industry Services (Drugs), Medical Review, and Policy and Regulations.

**Of Pharmaceutical Sciences:** Provides scientific support for drug compliance programs; develops scientific standards and conducts research on composition, quality, and safety of drugs; operates system for continuous appraisal and improvement of current and proposed drug standards and specifications; devises new chemical, physical, and biological methods to analyze drugs in pharmaceutical preparations and in tissues and body fluids; investigates mechanisms of the underlying chem-

ical reactions; explores use of novel instruments and equipment; designs and participates in collaborative studies to establish the reliability of new methods and of validating important discoveries relating to drug examinations; operates the National Center for Drug Analysis (St. Louis) and the National Center for Antibiotics and Insulin Analysis (Washington); cooperates with the Committee of Revision of the U.S. Pharmacopeia (USP) and the National Formulary (NF) to compose and assemble monographs for inclusion in official drug compendia.

**Divisions:** Drug Biology, Drug Chemistry, National Center for Antibiotics and Insulin Analysis, and National Center for Drug Analysis.

### **BUREAU OF VETERINARY MEDICINE**

Develops and recommends the veterinary medical policy of FDA on safety and efficacy of veterinary preparations and devices; evaluates proposed use of veterinary preparations for animal safety and efficacy; coordinates the veterinary medical aspects of the FDA inspection and investigational programs and provides veterinary medical opinion in drug hearings and court cases; plans, directs, and evaluates surveillance and compliance programs on veterinary drugs and other veterinary medical matters.

**Divisions:** Veterinary Research, Veterinary New Drugs, and Veterinary Medical Review.

### **REGIONAL FOOD AND DRUG DIRECTORS**

Represents the Commissioner in directing and coordinating FDA programs carried out through the DHEW Regional Offices and FDA District Offices in the Regions; encourages improved State and local food and drug consumer protection programs and participation in cooperative efforts with FDA; coordinates FDA assistance to States and localities in national disasters or other emergencies requiring FDA assistance; acts as information contact for DHEW Regions on FDA programs; coordinates FDA District programs with DHEW Regional Office operations; serves as primary advisor and informant to the DHEW Regional Director on FDA activities in the region; carries out programs as assigned in milk and food sanitation, shellfish sanitation, interstate travel sanitation, and product safety.

### **DISTRICT OFFICES**

Obtains compliance with laws and regulations enforced by FDA by conducting appropriate educational or enforcement activities; initiates and conducts educational and voluntary compliance programs; conducts investigations and inspections and analyzes samples of food, drugs, and other commodities; conducts administrative hearings on alleged violations; initiates enforcement action and recommends legal action to FDA headquarters, DHEW General Counsel, or the concerned U.S. attorney (where direct reference seizures are authorized) and assists in carrying out approved action; provides analytical and inspectional support in programs for which FDA is responsible.

# FDA's District Realignment

**O**n July 1 the reshaping of the regional operations of five agencies that provide Federal Government social and economic services go into effect as directed by President Nixon in Executive Orders issued March 27 and May 21, 1969. Under the presidential directive, 10 regions with the same boundaries and with regional headquarters in the same cities will be the basis for each agency's coverage over the country.

On April 1, in preparation for this regional streamlining, the Food and Drug Administration realigned the areas covered by some of its 17 Districts so that their geographic area coverage is balanced as optimally as possible among the 10 Federal regions and so that none of the District areas of operation will extend into more than one region. Under the combined realignment, five region and district boundaries will coincide, four regions will contain two districts each, and one region will include four districts.

The five Federal agencies involved in the regional realignment are the Department of Labor; the Department of Health, Education, and Welfare; the Department of Housing and Urban Development; the Office of Economic Opportunity; and the Small Business Administration. The 10 regions for these agencies with their headquarters and the States or territories within their respective boundaries:

**Region I**—Boston: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; **Region II**—New York City: New York, New Jersey, Puerto Rico, Virgin Islands; **Region III**—Philadelphia: Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia; **Region IV**—Atlanta: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee; **Region V**—Chicago: Illinois, Indiana, Minnesota, Michigan, Ohio, Wisconsin; **Region VI**—Dallas-Fort Worth: Arkansas, Louisiana, New Mexico, Oklahoma, Texas; **Region VII**—Kansas City: Iowa, Kansas, Missouri, Nebraska; **Region VIII**—Denver: Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming; **Region IX**—San Francisco: Arizona, California, Hawaii, Nevada, American Samoa, Guam, Trust Territory of the Pacific Islands, Wake Island; **Region X**—Seattle: Alaska, Idaho, Oregon, Washington.

The FDA realignment of District boundaries on April 1 in preparation for the effective date of the Presidential Order retains the Agency's 17 Districts and their headquarters cities, but their territories were changed in several instances to conform to the new

regional boundaries. The new District realignment:

**Atlanta**—Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee.

**Baltimore**—District of Columbia, Maryland, Virginia, West Virginia.

**Boston**—Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont.

**Buffalo**—New York (53 counties comprising the Northern and Western Judicial Districts and part of the Southern Judicial District).

**Chicago**—Illinois.

**Cincinnati**—Ohio.

**Dallas**—New Mexico, Oklahoma, Texas.

**Denver**—Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming.

**Detroit**—Indiana, Michigan.

**Kansas City**—Iowa, Kansas, Missouri, Nebraska.

**Los Angeles**—American Samoa, Arizona, California (nine counties comprising the Central and Southern Judicial Districts).

**Minneapolis**—Minnesota, Wisconsin.

**New Orleans**—Arkansas, Louisiana.

**New York**—Canal Zone, New Jersey, New York (nine counties comprising the Eastern Judicial District and part of the Southern Judicial District), Puerto Rico, Virgin Islands.

**Philadelphia**—Delaware, Pennsylvania.

**San Francisco**—California (Northern and Eastern Judicial Districts), Guam, Hawaii, Nevada.

**Seattle**—Alaska, Idaho, Oregon, Washington.

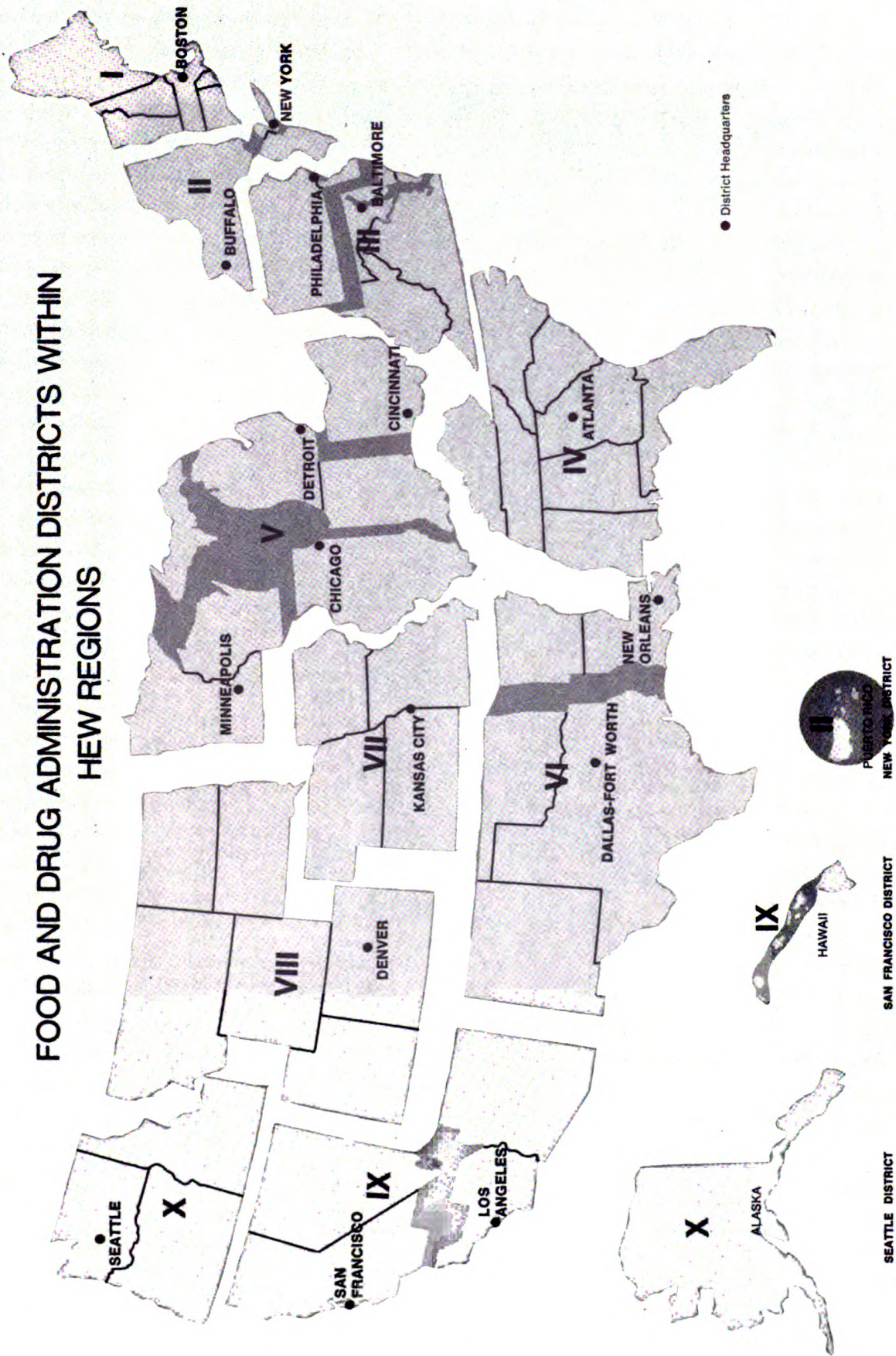
The District realignment is the most extensive in the history of the FDA and means that 12,803 regulated establishments have "changed hands" from one District to another. As an example of the volume of files and other records which were involved, more than 120,000 punch cards alone were transferred to other Districts.

The Districts are working to absorb the new firms into their inventories, revise their work plans, reidentify the establishments for data processing, etc. The transfers also affected Drug Registration files, which use the same identification as the District "Central File Number," and all headquarters computer data files, which were required to be changed so there would be no break in continuity of establishment records under the new identifications.

Although inspectors manning resident posts were reassigned where their cities became a part of other FDA Districts, there were no significant shifts in personnel among the District headquarters offices.



## FOOD AND DRUG ADMINISTRATION DISTRICTS WITHIN HEW REGIONS



# Bacterial Contamination of Topical Preparations: A Medical Evaluation

by William J. Evans, M.D.

**B**acteriological contamination of cosmetics and related topical preparations has received much publicity in the past 18 months. An apparent confrontation between Government and industry has occurred.

Contamination, when it occurs, violates the Food, Drug, and Cosmetic Act. We wish to place this problem in its proper perspective from a medical viewpoint. The radical extremes in points of view must be dispelled with a practical clinical assessment of the problem.

The bacteriologist views the problem, *per se*, identifying the type, virulence, and numbers of bacteria involved. Clinically this must be assessed under the light of the host factors. A combined approach is necessary to properly evaluate the hazard to health as it applies to the consumer. A combined medical and bacteriological decision must be reached.

To make this evaluation we must review the requisites for production of an infectious disease:

1. The host or prospective patient must lack sufficient immunity to the invading organism to become susceptible. Immunity is only relative and is never absolute. Immunity may be broken down in any individual by sufficient virulence, sufficient quantities of bacteria, or a temporary lack of resistance of the host. Debilitating diseases, malnutrition, trauma, corticosteroid drug therapy, age, and environment may be factors in lowering resistance.
2. The virulence of the bacteria is another variable factor. The mutation of bacteria frequently results from the use of antimicrobial agents with a change in flora and an overgrowth of resistant strains.
3. A sufficient number of virulent organisms may overwhelm the immunity of the host.
4. The mode of transmission involves the product, *per se*, or the contamination of another individual

through use of the product. The latter problem could affect premature infants, surgical cases, or debilitated patients on a medical ward, when product-contaminated physicians or paramedical personnel become carriers.

A factor that has been overlooked by many people is the relative loss of the effectiveness of antimicrobial drugs. Mutation of bacteria and progressive resistance to our antibiotic spectrum of drugs may usher in a new age of infection. Unfortunately, a couple of generations have been treated, at times inadequately, with powerful antimicrobial drugs for minor infections. The world believed that we had conquered infection. The therapy for infectious diseases since World War II may have resulted in a reduction in the natural immunity of man that had been developed for centuries. For this reason, sterile procedures and sterility take on an added significance. Iatrogenic infection must be seriously considered and eliminated by all concerned insofar as it may be prudently possible.

We cannot underestimate the significance of infection. We must free ourselves of the fallacy that infection can be easily and universally treated with success. This is not a world without infection and its associated morbidity and mortality.

Having generalized, we must reiterate that this discussion is pointed to the bacteriological contamination of topical applications. One of the primary functioning protective organs of man is his elastic, tough, and flexible skin. In this new decade when the problems of ecology and the total environment are justly being emphasized, the skin takes on added importance. It protects the internal environment of the body by preventing loss of electrolytes, water, etc. It has the important function of regulating the body temperature. It excludes to a great extent harmful substances such as chemicals and bacteria from the internal environment. Those as-







sociated with the cosmetic industry are well aware of the nails and hair that it propagates. Its melanin furnishes protection from the sun and a basic color foundation for cosmetics. Those in this industry are also, no doubt, aware of its excretory functions as well as the harmful effects of drying from overexposure to the sun or as a result of aging. It is a mirror of health and beauty as well as a mirror of disease.

Aging of the skin is progressive and is a fact of life. No one can turn back the physiological clock but the individual can through proper diet, exercise, and preventive care help delay the aging process. Once that process has become apparent, cosmetics are an aid in masking it. Although cosmetics enhance beauty and are involved in giving a psychological lift that buoys the spirit, it is essential that they cause no serious harm. Relative safety is of the essence. Thus we must approach adverse effects by considering the good that is accomplished in relation to the harm that may ensue.

Everyone is constantly bombarded by environmental bacteria. The healthy intact skin withstands this attack. Serious infections of the intact skin in the healthy individual are relatively rare. Tissue damage or a piercing of the skin armor, combined with decreased immunity, are necessary precursors to infection in most cases. The healthy individual has a great resistance to the flora of bacteria normally found on his skin, in his body, and in his usual environment. However, lowered immunity through debilitating diseases, drug therapy, or an unusual environment may allow serious infection to take place.

Clinically the bacterial contamination of topical creams and ointments or dusting powders must be placed in perspective. Examples of the overall hazards to health involving drug actions and reactions and bacterial contamination of other articles under the Food,

Drug, and Cosmetic Act may increase our understanding of the problem. Relative safety and efficacy are keys to the problem. For example, we may accept the relative lethal toxicity of the chemotherapeutic drug, methotrexate, because it has saved the lives of 60 percent of patients with choriocarcinoma even after metastasis has taken place. On the other hand, serious side effects cannot be accepted in symptomatic cold therapy.

A recent problem involving the bacterial contamination of catheter kits shows the various hazards that may be encountered. We must note that kidney infection, after the acute phase, becomes a silent, progressive disease. In this case a double-barreled contamination was involved. The detergent containing a quaternary ammonium compound was bacterially contaminated as was the gel used as a lubricant for the sterile catheters.

Clinical evaluation of hazard to health varied because of the types of catheters used and the varying clinical conditions under which they were used. The ordinary simple urinary catheter contaminated by the lubricant or by use of the detergent involved a minor-to-moderate health hazard that was possible to unlikely, depending on the relative condition of the patient. However, in those kits containing Foley catheters the hazard to health was magnified. Foley catheters, as retention catheters, are usually used postoperatively and cause some retention of urine (a fertile field for growth) with the result that the hazard to health becomes moderate to serious and is possible to probable. A serious virulent pathogen in large numbers would make the potential hazard serious.

With this background let us examine the bacterial contamination of topical cosmetics and drugs that are used in various environments. The normally healthy individual using a hand lotion or moisturizing cream daily would probably be unaffected by pathogens unless

other rare factors were involved. Breaks in the continuity of the skin caused by trauma, eczema, burns, or by chronic irritation in such areas as the eyelids could change that picture.

*Pseudomonas* contamination in eye shadow, mascara, or eye lotion or drops could possibly be very hazardous. Keep in mind that *Pseudomonas* infection is highly resistant to therapy. The literature reports approximately a hundred cases of *Pseudomonas* infection of the cornea resulting in loss of the eye. Statistically speaking, this figure is but the top of the iceberg.

Although a serious result is relatively rare, the wider use of contact lenses, particularly by women, and the frequent occurrence of at least microscopic abrasions may increase this hazard a hundredfold. But rare in occurrence or not, it is not in any way justified if it is preventable. Statistics are a poor answer for the victim in whom the result has been 100 percent hazardous.

Another principal area involving a hazard to health from bacterial contamination of creams and lotions is in the environment of hospitals, convalescent nursing homes, and homes for the aged. Patients who are debilitated by chronic diseases such as diabetes or who are bedridden for any reason, and who are subject to decubital ulcers, are susceptible to infection that may be lethal. Many of these patients are being treated with corticosteroid drugs, which further reduce their resistance to the point where the virulence and the number of bacteria become less important as factors leading to massive infection in the patient.

Contaminated hand creams used by nurses and surgeons may result in iatrogenic infection of wounds or may result in a break in sterile surgical technique. Newborns, particularly those that are premature, have little resistance to infection, the umbilical cord frequently being the doorway to septicemia.

There is no doubt that the problem of microbial contamination of products is not a new one, but we have only recently become seriously aware that it exists. The question may arise that, if this is a problem, why were we not clinically aware of this source of infection years ago? For the past two decades infection has been brushed aside, medical sterility techniques have been

neglected, and when infection occurred, we simply used the appropriate antimicrobial drug with miraculous results. It was said that the physician would rather treat a patient for pneumonia than for the common cold; treatment of the former was faster and more effective.

Although we were aware of a cause and effect where infection was concerned, we were more interested in therapy and cure. Cause and effect are easily overlooked. How frequently have bacterially contaminated topical drugs or cosmetics caused serious infection? This is certainly unknown. The problem of cause and effect frequently evades even the most conscientious observer. For example, the relationship of congenital deformities to German measles in the first trimester of pregnancy was discovered only within the past two decades. This is astounding, considering the long relationship of childhood diseases to pregnancy.

Teamwork is necessary if we are to achieve the common goal—the greatest attainable protection for the consumer. Spoilage and degradation of products by bacteria are important, but far more important to the consumer is the potentially harmful result of bacterial contamination. The microbiological monitoring of raw materials and the finished product should be extended into the marketplace. Health of personnel, hygiene, and sanitation are essential elements of quality control. Those topical products for use in the environment of the hospital should be sterile and packaged in dispensing units that will help prevent contamination through use. The time has come when a qualified bacteriologist is a first string player on the quality control team. Industry as well as Government must develop an acute perception of the threats by bacterial contamination of products to public health.



William J. Evans, M.D.,  
Bureau of Drugs,  
joined FDA in October  
1960.



# The Ritts Committee

by Berwin A. Cole, Ph.D.

When Dr. Charles C. Edwards assumed the post of Commissioner of Food and Drugs, one of his first impressions was that the Food and Drug Administration's relationship with the other Federal health agencies seemed to be one of being "on the outside looking in." This puzzled and troubled him.

As a physician and as a manager, he felt FDA should not only be a full-fledged member of the Federal health community but probably be its most important member in the light of the immediate and direct impact of its mission on the health and well-being of the American people. Indeed, in many instances, its actions have international import as well. Further, regulatory decisions must be studied and deliberate and based upon the most complete and the soundest scientific data available. Given these considerations, it was hardly surprising that as an early order of business the Commissioner turned his attention to the Agency's science activities. Instead of committing himself irrevocably to those values and methods that had furnished grounds in the past for questions about and criticism of the Agency's scientific capabilities, he decided to go outside FDA to the Nation's scientific community for a fresh look and a fresh appraisal.

The Food and Drug Commissioner didn't spend his time or energy propounding an imposing name for his new ad hoc science advisory committee. "Any name I give it will be interpreted and mas-



Four of the five members of the Ritts Committee (below) were sworn in March 12. At the ceremonies (left to right): Charles C. Edwards, M.D., Commissioner of Food and Drugs; Rupert F. Moure, Assistant Commissioner for Administration, who is administering the oath; and members Roy E. Ritts, M.D., chairman; Lauren A. Woods, Ph.D.; Willard A. Krehl, Ph.D., M.D.; and J. Richard Crout, M.D.; Marion W. Anders (photo, upper right), D.V.M., Ph.D., was sworn in the next day. Berwin A. Cole (photo, upper left), Ph.D., author of this article and staff director of the committee, joined FDA in August 1969 as Deputy Associate Commissioner for Science.



saged and meanings read into it that just don't exist." So this important group, like many others on the Washington scene, has taken the name of its chairman. Dr. Edwards wanted a committee of a size compact enough to be able to operate effectively. He insisted that its members be men of demonstrated competence and productivity, men who had earned the respect of their peers, but who had not so committed themselves in the past by public pronouncements, published articles, or congressional testimony that they would feel compelled to spend their time defending past positions and postures.

The chairman of the Ritts Committee is Roy E. Ritts, M.D., whose specialty is microbiology. Dr. Ritts was a research fellow at Harvard Medical School, a visiting investigator at the Rockefeller Institute for two years, chairman of the Department of Microbiology and Tropical Medicine at Georgetown University School of Medicine, and is currently head of the Section on Microbiology at the Mayo Clinic and professor of microbiology, School of Medicine, University of Minnesota.

The other members are J. Richard Crout, M.D., Department of Pharmacology, University of Texas, Southwestern Medical School at Dallas, who was a clinical associate at the National Heart Institute for three years and a research fellow in pharmacology at Harvard Medical School; Willard A. Krehl, Ph.D., M.D., professor of preventive medicine at Jefferson Medical College, who was president of the Society of

Clinical Nutrition; Marion W. Anders, D.V.M., Ph.D., professor of pharmacology, University of Minnesota; and Lauren A. Woods, Ph.D., M.D., professor and head of the Department of Pharmacology, Iowa Medical School, University of Iowa. Dr. Woods is president-elect of the American Society for Pharmacology and Experimental Therapeutics and president-designate of the Federation of American Societies for Experimental Biology. On July 1, 1970, he assumes the post of vice president for health sciences, Virginia Commonwealth University. The staff director is Berwin A. Cole, Ph.D., Deputy Associate Commissioner for Science.

The Commissioner's charge to the committee was a broad one—to review and evaluate the total scientific efforts of the Food and Drug Administration, and to advise him on all aspects of FDA's science activities, including research planning, research priorities, the use of grants and contracts, utilization and structure of the District and field laboratories, research reporting, and interdepartmental and interagency science relationships.

The first meeting of the Ritts Committee was held in Rockville, Maryland, at the Parklawn Building, on March 12 and 13. Presentations were made by various staff members of the Office of the Commissioner and of the three Bureaus. Plans have been made by the Committee to visit various District laboratories and National Centers and a second meeting was held in April.

Already during this orientation period, the members of the commit-

tee have demonstrated perceptiveness and grasp of the problems of science by identifying areas they wish to study in depth. They have identified, for example, the problems FDA scientists encounter in trying to balance commitments to pressing problems as compared with long-range problems, and reacting to crises instead of thinking about anticipated problem areas; the decision-making process and how scientists can follow their input and feel their participation; the balance between intramural and extramural research; how scientific priorities are arrived at and set; and science "housekeeping" including the ways data are stored and retrieved and reported.

The members are enthusiastic about the potential of their contributions, serious about the import of the assignment, and willing to contribute considerable time and travel in the months ahead. It is not anticipated that they will produce a single "magnum opus" at the end of their deliberations. Instead, they will be sending a continuous stream of suggestions to the Commissioner for consideration and action as they go along, and a final document that will probably be one of the bases upon which science planning for FDA can be effected.

Commissioner Edwards has placed great emphasis on the importance of the committee to him and to the FDA. The members in turn are responding to this opportunity to serve the health needs of the Nation. Their enthusiasm and constancy of purpose augurs well for all.



# Looking at the Nation's Drugs

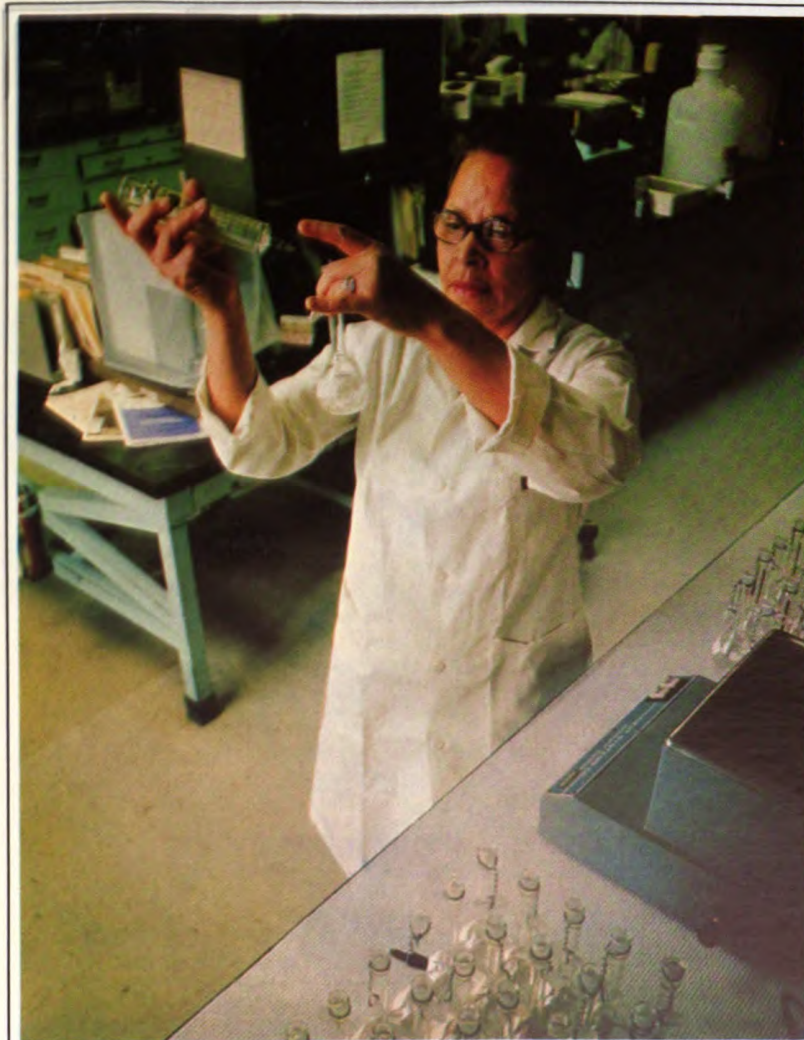


FDA's National Center for Drug Analysis in St. Louis was established in July 1967 to inaugurate mass production techniques and automated or semiautomated procedures for chemical and physical analyses of drugs. The need for speeding up analyses had been indicated in the increasing number of drugs being recalled because of various deviations in purity and potency from specifications and requirements in the United States Pharmacopeia and the National Formulary, or in new drug specifications as described in New Drug Applications submitted to the Agency.

Agency projections indicated that an increasing number of analyses would be required yearly—far more than the number then being performed on a unit production basis in district and headquarters labs—to assure the quality of drugs in the marketplace.

The Center was established after a pilot study a few months earlier on the feasibility of setting up large scale analytical operations (see FDA Papers, May 1967). NCDA is a division-level field installation in the Bureau of Drugs' Office of Pharmaceutical Sciences, headed by Dr. Daniel Banes, and the Center is directed by Dr. Arthur W. Steers.

The Center currently has a staff of 30 professional scientists and 14 supporting administrative and laboratory personnel. In its first full fiscal year (1968) it analyzed 7,227 samples, in fiscal 1969 it analyzed 9,395 samples, and in fiscal 1970 will examine an estimated 12,000 samples. The Center's analyses of samples from all known manufacturers of a particular drug not only is effective in pinpointing violations for regulatory action, but also enables FDA to assess the quality of the entire national supply of that drug.





This automatic pipet (top left) designed and built at the Center adds a pre-set amount of solvent to vials containing individual tablets to produce solutions to be put on the autoanalyzer. The pipet frees a chemist from a boring, repetitious task.

The Cahn autobalance (center left) automatically weighs 25 individual tablets or capsules a minute, enabling a chemist to determine weight uniformity, a measure of how well the formulator has adjusted his machinery. The chemist is weighing sodium warfarin tablets.

This automatic Cary 15 (next to bottom, left) is determining the amount of methylergonovine maleate present in tablets by measuring the light absorbed by the solution. It can be rigged to measure over 40 drug samples an hour unattended, compared to 10-15 an hour by manual analysis. This instrument normally is used for high precision checking of samples suspected to be out of limits based on results from the autoanalyzer.

This autoanalyzer (bottom left) simultaneously measures both the methenamine and sodium biphosphate present in this formulation and makes a readout on each in different colored inks on the graph. It produces 15 analyses an hour, compared to 15 a week for a chemist using manual methods.

Corticosteroid tablets in flasks with solvent are placed in an ultrasonic vibrator to speed disintegration (far left), then are processed by the auto-analyzer (far right, bottom), yielding a red-colored solution that is read by a colorimeter and the percentage of the drug printed on a tape. The unit can handle 25 analyses an hour, compared to 10 a day for a chemist without the automated equipment.

Procainamide tablets are put in solution and placed on the titralyzer (far right, top), which measures the amount of sodium nitrite reacting with the procainamide, enabling the chemist to calculate the amount of the drug present. The instrument frees the chemist from doing the titrations by hand.







In an automated gas-liquid chromatography identification-measurement method to be put into operation soon (two top photos and one below right), solutions of drug tablets or capsules are injected by syringe into small plastic capsules, which are placed in holes on a turntable holding up to 36 capsules that is mounted on the GLC, into which they are fed one at a time. The automatic GLC can be left unattended to run samples during nonworking hours.

Optical isomers are molecules so chemically similar that it's easy to mistake one for the other in formulating drugs containing them. This digital polarimeter (center left) can distinguish between optical isomers and measure the amount of each by measuring the rotation of specially treated (polarized) light waves. Watching Don Cox, chemist, operate the instrument are (left to right) Lawrence Jones and M. P. Goldman, Analytical Section Chiefs.

In bottom left photo, a special gas-liquid chromatograph (in background) and the infrared spectrophotometer (in foreground) detect and measure impurities in medicinal gases such as carbon dioxide, and oxygen. Impurities are separated and measured on the GLC column. The infrared spectrophotometer measures absorption patterns of heat energy, which are characteristic for every known substance except optical isomers, and thus can measure and identify traces of toxic impurities.



# The Science Advisory Committee

by Dale R. Lindsay, Ph.D.

In the first few days after assuming the position of Commissioner of Food and Drugs, Dr. Charles C. Edwards decided that a Science Advisory Committee was needed to advise him on the scientific issues that would require him to make a decision or to take a position. To be fully effective the Committee would have to anticipate the problems around which the issues might arise and inform itself of all the facts that could be assembled concerning these problems. Thus, in carrying out its mission, the Committee must first accomplish a high degree of communication within the whole FDA.

The problem of effective communications is always great, irrespective of the structure of an organization. The reorganization of FDA Bureaus along product lines accomplishes the pinpointing of responsibility for the regulatory actions on the products being controlled, but it does not improve communications between the Bureaus. Each Bureau could conceivably become an island with relatively little need for interaction with the other Bureaus were it not for the Commissioner's Office and certain Committees which may provide for Bureau interaction or common services.

To counteract this isolation tendency and to insure that communications are prompt and relevant, Commissioner Edwards requested each of the three Bureau Directors to designate a representative, other than himself, to serve as a member of the Science Advisory Committee. Since it is imperative that this Bureau representative be fully aware of all the scientific activities and developments within his Bureau, it was suggested that this person should be the individual who serves as the Assistant Bureau Director for Scientific Coordination. Regardless of the intra-Bureau title of the Committee

member, it is his responsibility to keep fully informed of pertinent Bureau activities and to see that his Bureau Director is also informed. Following meetings of the Committee it is the responsibility of each Committee member to advise his Director and other appropriate members of his Bureau of any Committee actions that in any way affect them. The role of the Bureau representatives is admittedly difficult but of the utmost importance.

The Chairman of the Science Advisory Committee is the Associate Commissioner for Science and the Vice Chairman is the Deputy Associate Commissioner for Science. The role of Executive Secretary is filled by a member of the Associate Commissioner's (for Science) staff. Recommendations of the Committee will be transmitted immediately by the staff to the Commissioner for his consideration. Agenda items for Committee meetings should be routed through the Bureau representatives to the Office of the Associate Commissioner for Science.

An important but nonvoting member of the Science Advisory Committee is the Associate Commissioner for Compliance, who participates in all deliberations and provides resources otherwise lacking. Dr. Edwards' decision that the Associate Commissioner for Compliance should not vote on scientific issues was based upon his desire to emphasize that the recommendations of the Committee were based upon the scientific evaluations made rather than upon considerations of compliance problems. However, it has been amply demonstrated that compliance problems must be considered simultaneously with science problems in order to act in the public interest; recommendations undoubtedly will reflect these dual considerations.

The difficult role of the Bureau





Dale R. Lindsay, Ph.D., Associate Commissioner for Science, joined FDA in that position in August 1969.



representative will be enhanced greatly if the scientists and administrators in his Bureau will make a special effort to keep him informed of their activities, needs, and problems. This will be particularly true in those many instances when inter-Bureau and inter-Agency activities are involved. A few moments devoted to better communications may be the most productive of the day!

While the FDA, as an agency, is constantly seeking improvement in the decisionmaking process, it also recognizes the value of deliberate procedure in arriving at conclusions. To insure that the decisions of this Committee, upon which recommendations to the Commissioner are made, are truly reflective of adequate deliberations both in the Bureaus and in the Committee, most agenda items will be studied in two successive meetings of the Science Advisory Committee before a recommendation is forwarded to the Commissioner. Emergency items and items not involving policy or long-range consequences may be exceptions. For example, an item that may involve policy or long-range implications will usually be presented to the Committee prior to

the meeting at which it will receive its initial review. This is designed to encourage the Bureau representative to discuss the item with appropriate persons in his Bureau so that he may represent them in the Science Advisory Committee deliberations. By deferring a decision until at least the second review of the item by the Committee, it is possible, and highly desirable, for the Bureau representative to report back to his colleagues the salient features of the other Bureau representatives' discussions and points of view. Further consideration by the Committee at a second meeting should thus encompass a thorough and in-depth review by a wide spectrum of Bureau personnel.

With the Science Advisory Committee fully operational, we should avoid any further scientific surprises upon the Commissioner and his staff, and in turn upon the DHEW Assistant Secretary for Scientific Affairs and the Secretary. It is to the interest of all of us, and of the public we serve, to make every effort to keep our representatives promptly and fully informed of all developments that come to our attention.

Members of the Science Advisory Committee and other FDA staff people making presentations at a committee meeting are (clockwise around table from right foreground) Dale R. Lindsay, Ph.D., associate commissioner for science, chairman; John P. Hile, assistant commissioner for field coordination; Fred Kingma, D.V.M., deputy director, Bureau of Veterinary Medicine, member; John J. Schrogie, M.D., director, Division of Research and Liaison, Bureau of Drugs, member; R. E. Duggan, deputy associate commissioner for compliance, representing Associate Commissioner Sam Fine, member; Robert A. Littleford, Ph.D., acting director, Office of Research and Training Grants, Office of the Associate Commissioner for Science; Jack D. Findley, executive officer, Office of the Associate Commissioner for Science; Kenneth E. Taylor, Ph.D., director, Office of International Affairs; Raymond Shapiro, Ph.D., research chemist, Bureau of Foods, Pesticides, and Product Safety; Herman F. Kraybill, Ph.D., assistant director for scientific coordination, Bureau of Foods, Pesticides, and Product Safety, member; Berwin A. Cole, Ph.D., deputy associate commissioner for science.



# Oral Contraceptives: A Status Report

by John J. Schrogie, M.D.

Since the publication of the Second Report on Oral Contraceptives by the FDA Advisory Committee on Obstetrics and Gynecology (August 1, 1969), lively discussion has resulted. This report summarized many significant observations made from the time the last report was published in 1966 (see FDA PAPERS, September 1969). Following review of the information that was considered, it was clear that certain revisions in the present labeling of the oral contraceptives were needed.

As a result, particularly of the study on thromboembolism performed under contract with FDA by Philip E. Sartwell, Professor of Epidemiology, Johns Hopkins University School of Hygiene and Public Health, revisions in that portion of the labeling concerning this disease were given active consideration. This study encompassed a review of hospital records of women who had survived episodes of thromboembolism and included study of suitable controls; the information was confirmed and completed through home interview with the selected patients.

In addition to confirming an association between thromboembolism and the use of oral contraceptive drugs, an unexpected finding was that the sequential type of oral contraceptives seemed to be associated with a disproportionate share of the risk. Although this observation was not regarded as completely conclusive, it was felt to be of sufficient importance to receive special mention in the labeling of these drugs.

After some months of discussion and careful review of the data, FDA and industry in late 1969 agreed upon a final version of the revised labeling. This finding was of particular importance and deserves a special note because it was the first clear suggestion that there might be differences in risks between marketed drug products.

At approximately the same time, other findings were reported by the British Committee on the Safety of Drugs. These indicated that oral contraceptives containing relatively higher doses of estrogen seemed to be associated with the greater risk of thromboembolism. Although detailed information about these findings was not available at the time, the use of lower dose estrogen

products was recommended in Great Britain. These findings were also not inconsistent with the findings of the Sartwell study. More recently, in March 1970, at the invitation of the British officials, the Commissioner of Food and Drugs headed a delegation of FDA and National Institutes of Health representatives which went to England to review and confer on these findings. The results are presently under intensive review.

The new findings were felt to be of sufficient interest to stimulate the Commissioner to prepare a letter to all physicians advising them of these latest results. This letter, addressed to physicians, hospital pharmacists, and hospital administrators, and sent on January 12, 1970, was the first on the subject since June 1968. The letter also emphasized the importance of a full discussion between physician and patient of the potential side effects of the oral contraceptives.

To assist in the communication of this information to the patient, the Commissioner decided that a brochure should be included in packages of these drugs. This would serve as a reminder about certain side effects and stimulate the patient to report unusual symptoms promptly to her physician or to return for regular physical examination. An early draft of the brochure was first made public on March 4, 1970, at Senate hearings called by Senator Gaylord Nelson to hear testimony from various experts about the safety of oral contraceptives. More recently a shorter draft has been proposed (see page 25).

This action represents a unique but not unprecedented move by FDA in providing information about prescription drugs directly to the consumer. The development seemed warranted in this case because these relatively potent drugs are in long-term use by relatively healthy women who specifically choose this method of drug therapy.

Present information continues to support the virtually unexcelled clinical effectiveness and acceptability of the hormonal contraceptives. Although further information about side effects, both definite and surmised, is being collected (see FDA PAPERS, June 1969), several interesting research developments suggest that these risks

# FDA CURRENT DRUG INFORMATION

NEWS AND REPORTS OF INTEREST TO PRACTICING PHYSICIANS. ISSUED BY THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

## Oral Contraceptives and Thromboembolic Disorders

*This latest report on the relationship between the use of oral contraceptives and thromboembolic disorders reflects the Food and Drug Administration's evaluation of recent data and clinical experience both here and abroad.*

*On the basis of this information, FDA recommends that the practicing physician, in his choice of an oral contraceptive, consider that a product containing a lower dose of estrogen should be prescribed if it is otherwise effective and acceptable to the patient. The higher dose products should be reserved for use when necessary.*

*The report follows:*

### DESCRIPTION

At present there are a number of effective oral contraceptives available for prescription use. All of the currently marketed oral contraceptives in the United States are comprised of estrogens and progestins administered in either combination or in a sequential fashion. All of these have been approved as safe and effective by the Food and Drug Administration in that they are extremely effective and the benefit conferred by this high degree of efficacy in preventing pregnancy is considered to outweigh the possible hazards.

Because of the widespread use of these drugs in women who for the most part are in good health, any indication of an avoidable hazard is of extreme importance. The increased risk of thromboembolic disorders among users of oral contraceptives compared with non-users has been established and has been the subject of communications by the Food and Drug Administration to the prescribing physicians via product labeling and warning letters.

In the controlled studies conducted prior to marketing of the oral contraceptives, the association of thromboembolic disorders and the use of these drugs was not discerned. This may be explained by the fact that although the incidence of such disorders is increased by the administration of oral contraceptives, it is still of such a low order of magnitude that valid rates of incidence could not be obtained in the relatively small sample size in the premarketing clinical trials.

### INCREASED RISK

Data establishing the increased risk of thromboembolic disorders among users of the products have been derived from retrospective analysis of medical records. In these reviews, previous efforts to establish differences between various types of products were unsuccessful except that

in one study (Sartwell) an unquantifiable increase in this risk was discerned in users of the sequential products compared to users of the combination products. Earlier British studies had attempted without success to determine whether there was a relationship between the dose of estrogen and the risk of thromboembolic disorders.

In December 1969 the British Committee on the Safety of Drugs recommended to all practicing physicians in that country that the lower estrogen dose products be used for contraceptive purposes in preference to the higher estrogen dose products. The data on which this action was based are derived from an analysis of case reports submitted on a spontaneous basis to the Committee by some of the practicing physicians of the United Kingdom. Market surveys were used to determine the percentage of each product in the total sales. Additional data were obtained from national adverse reaction reporting systems in Denmark and Sweden. These data have recently become available to the Food and Drug Administration and its consultants.

### ESTROGEN RELATIONSHIP

Notwithstanding the inherent limitations of a study of this sort, it can be accepted as suggesting a relationship between the risk of thromboembolic phenomena and the dose of estrogen. The role of the progestational agents in influencing the risk is unclear. It is clear that further study of the problem is necessary.

The Food and Drug Administration and others are currently conducting studies to further elucidate and quantify what risks are involved with the use of various types of oral contraceptives.

### FINDINGS AND RECOMMENDATIONS

Based on the various studies cited above, as well as on studies and clinical experience implicating estrogen itself in causing an increase in the risk of thromboembolic disorders when used for purposes other than contraception, the Food and Drug Administration position may be summarized as follows:

- ☐ *Use of the oral contraceptives increases the risk of thromboembolic disorders.*
- ☐ *There is evidence that estrogens per se increase the risk of thromboembolic disorders.*
- ☐ *Data are inadequate to delineate differences between specific products but indicate a trend toward increased risk of the disorder with higher estrogen dosage.*
- ☐ *Good therapeutics would indicate the use of the lowest effective dose of estrogen that is otherwise acceptable.*

April 24, 1970

This is one of FDA's new Drug Newsletter series being distributed to practicing physicians, pharmacies, and departments of pharmacology in medical schools. The Drug Newsletters will provide information that the Agency considers important in carrying out its responsibilities under the Food, Drug, and Cosmetic Act.

## **ORAL CONTRACEPTIVES**

### **(Birth Control Pills)**

The oral contraceptives are powerful, effective drugs. Do not take these drugs without your doctor's continued supervision. As with all effective drugs, they may cause side effects in some cases and should not be taken at all by some. Rare instances of abnormal blood clotting are the most important known complication of the oral contraceptives. These points were discussed with you when you chose this method of contraception.

While you are taking this drug, you should have periodic examinations at intervals set by your doctor. Notify your doctor if you notice any of the following:

1. Severe headache.
2. Blurred vision.
3. Pain in the legs.
4. Pain in the chest or unexplained cough.
5. Irregular or missed periods.

may be minimized in the relatively near future. Although the significance of many of the metabolic effects produced by the oral contraceptives will be uncertain for some time, it does appear that certain ingredients of the presently available formulations have a varying propensity for causing such changes. It seems that a rational course for the future, which can be fairly rapidly explored, is to identify those drugs which produce the least disturbance in biochemical function. It is to be hoped that a consistent pattern of response will emerge and that such effects thus will be minimized with no sacrifice of efficacy.

As corollaries to this idea, other areas for investigation have recently been more clearly identified. For example, much more intensive studies of the lowest dose of drug which will still have a high degree of effectiveness should be rapidly undertaken. It will also be a high order of priority to improve surveillance methods for adverse drug reaction reporting.

Although presently available oral contraceptives are not ideal, there does not appear to be an effective successor or alternative near the clinical trial or marketing stages at the present time. Research on reproductive physiology to assist in the development of better and improved methods is underway and is supported by both Government and industry. Research on the presently available oral contraceptives does suggest that potential risks will be elucidated and minimized within the foreseeable future.



John J. Schrogie, M.D., Director of the Division of Research and Liaison in the Bureau of Drugs, joined FDA in 1967.



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# field reports

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**ATLANTA DISTRICT** The Georgia Department of Agriculture and FDA's Atlanta District cosponsored a course in sanitation and warehouse inspection which graduated 34 professional sanitarians during February 1970. The sanitarians work for the Consumer Protection Division of the Department. Other groups assisting in course presentations included the National Communicable Disease Center and the U.S. Department of the Interior's Bureau of Sport Fisheries and Wildlife. Such training courses are part of the State/Federal program being carried out in Georgia.

During a three month period, Atlanta District collected some 60 samples of fresh fruits and vegetables imported through ports of entry in Florida, to test for pesticide residues. The produce, collected from December 1969 to February 1970, included cucumbers, cantaloupe, Uglis (registered brand name for a type of citrus fruit), tomatoes, okra, green peppers, egg plant, and yuca (cassava). The District found, after examination, that none of the products contained pesticides in excess of established tolerances. The examined produce was imported from Mexico, Jamaica, San Salvador, Santo Domingo, Guatemala, and British Honduras.

**BALTIMORE DISTRICT** A lot of 10,000 pounds of yellow cornmeal that became insect and rodent contaminated during a yearlong wait for export orders was seized during February by a U.S. marshal. The meal, in possession of the Western Maryland Railway Co., Baltimore, had originally been received from a cereal mill in Illinois.

**BOSTON DISTRICT** The District offices welcomed an Italian Government official and an Italian businessman who came to obtain information on U.S. labeling and import requirements for a line of spaghetti and macaroni products they hope to export to the United States. Pasquale Giordano, who represents the Italian Trade Commission in Boston, accompanied Vincent Sallusto of the Pasta Ferrara Co., Naples, Italy.

A newspaper contacted Boston District offices recently concerning the sale of cyclamate-containing beverages as part of a fund-raising effort by a Connecticut branch of the YWCA. About 3,000 cases of the soft drink had been donated to them in mid-December by a soft drink manufacturer. After two warnings by the District office, the YWCA decided to destroy its remaining stocks of the soft drink under State of Connecticut supervision.

**BUFFALO DISTRICT** Five chemists from a drug firm undergoing Intensified Drug Inspection in the Boston

District will receive a week's intensive training at the District laboratory to upgrade their level of proficiency. District inspection had indicated the chemists were not adequately trained or sufficiently experienced in spectrophotometric analysis.

The District recently denied entrance at the port of Utica to a 40,000-pound shipment of Italian Pecorino cheese, made from ewe's milk, when examination showed the presence of residues of benzene hexachloride, a pesticide chemical.

**CHICAGO DISTRICT** A Milwaukee resident bought a bag of pretzels, ate one, and experienced a burning sensation in his mouth. The consumer reported the incident to the Milwaukee resident post, which in turn reported it to the Chicago District headquarters. The District initiated an immediate inspection of the pretzel manufacturing firm, located in Chicago, and discovered that a batch of pretzels had been produced by a night shift which had accidentally used a double solution of sodium hydroxide, a general purpose food additive, in the glazing bath. The firm had not discovered the mistake, and had shipped part of the batch to Milwaukee. The firm's management agreed to recall the Milwaukee stock, and also picked up and voluntarily destroyed the remaining stock in the presence of two FDA inspectors.

This swift action resulted in minimal distribution and there were no other reported injuries.

A new unwieldy, and at first temperamental lab worker recently joined the Chicago District. Known as Digital PDP-12A, the newcomer required a ten-man crew (including the acting regional director) to get her transferred from the 11th floor freight elevator to the passenger elevator and finally, to the 12th floor lab. Larry Alber, computer project officer, and a company service man managed to get Digital operational, but after five hours, she quit. A faulty diode was replaced with one rushed from Massachusetts via air, and on March 6 the District's Digital Laboratory Computer started work again. Initially she will be interfaced to the BC-10 Gas Chromatograph for pesticide analysis.

**CINCINNATI DISTRICT** Robert E. Keating, District food and drug officer, and Catherine A. Knarr, consumer specialist, appeared recently on a popular television daytime show called "Bob Braun's 50-50 Club," where they discussed FDA's role in combating quackery and displayed a number of devices and other products against which FDA has taken action. The broadcast originated in the studios of WLW-TV in Cincinnati. The program is said to reach about 200,000 people in the

tri-State area of Ohio, Indiana, and Kentucky.

The District's first detention of imported pottery because of its lead content was made recently at Chattanooga, Tennessee. The product, a novelty item invoiced as "Hillbilly Whiskey Sets," originated in Japan and was designated as "Rockingham Ware." Although the sets have the appearance of a novelty item, they could be used for storage of beverages and other food items.

**DALLAS DISTRICT** Four officers of the Fourth U.S. Army Veterinary Corps visited Dallas District offices recently, where arrangements were made to provide them with copies of warning letters, post-inspection letters, and reports of analysis which FDA issues to any of the 700 firms in the region with whom the Army contracts for military food purchases. The four officers agreed in turn to notify FDA of unsatisfactory conditions they encounter during their inspections.

Regional Director Louis Weiss participated in three workshops which had a combined audience of 360 persons during an eight-day period in February. The workshops included: the 19th Cottonseed Processing Clinic held in New Orleans February 16-17 which about 150 representatives of the cottonseed milling industry attended; the workshop for the rice industry held in Brinkley, Arkansas, on February 19, and attended by 125 persons representing 40 firms; and a highly successful drug workshop presented by Dallas FDA District in Austin, Texas, on February 24, and attended by 85 persons representing 30 firms. Dr. Daniel Banes, FDA's Director of Pharmaceutical Chemistry, also participated in the drug workshop, which was held in cooperation with the North Texas Drug and Chemical Association and the University of Texas College of Pharmacy.

**DETROIT DISTRICT** FDA's Detroit and Seattle Districts cooperated with officials of the States of Alaska and Michigan to monitor shipments of Michigan coho salmon containing DDT and intended for use as fish bait to prevent any diversion into human food channels (see also Seattle District and March 1970 FDA PAPERS).

Labeling inadequacies alerted the District to potentially harmful ingredients in a permanent eyebrow dye offered for importation from Germany. The dye, in two parts, contained a label statement that in case of loss of the powder to be mixed with the dye color, the user could substitute hydrogen peroxide. This indicated to District personnel that there could be oxidation of an organic substance to produce a toxic chemical. However, the labeling did not identify the dye substance nor contain the precautions that are required for most permanent dyes. The consignee claimed the product was harmless and that he had imported it for about 15 years. But District lab analysis showed the dye contained para-

phenylenediamine, a substance known to cause serious eye injury. Thus, the product was denied entry.

**KANSAS CITY DISTRICT** Hazards from Freon-contaminated liquified petroleum gas were averted recently when cooperating officials in the Wichita, Kansas, area promptly informed FDA's Kansas City District that they had discovered contaminated LP gas in home workshop-type containers. The presence of Freon in LP gas would produce toxic phosgene gas when burned. A joint State/Federal investigation showed the LP gas was contaminated with approximately 1½ percent Freon. The Wichita distributor withheld 3,240 retail-size cans from the market and under FDA supervision they were subsequently destroyed voluntarily along with 11,952 retail-size cans found at the manufacturing plant. Another 3,392 gallons of the bulk product remaining from previous bottling was sold and shipped to a Kansas refinery for other, nonhousehold use. None of the contaminated LP gas reached the market.

**LOS ANGELES DISTRICT** The District recently seized 3,000 pounds of shelled pecan pieces that were contaminated with *E. coli* as a result of insanitary manufacturing operations. The nuts, packed by Funsten Nut Division of Pet, Inc., Andalusia, Alabama, had been shipped to the firm's warehouse in Los Angeles, where seizure was made.

Allegations concerning the therapeutic properties of a medicine made from the leaves of a common desert shrub were the basis of recent District seizures. The medicine, called Cinema tablets, was represented to be an effective treatment of cancer, peptic ulcer, leg ulcers, warts, pimples, and impaired breathing. The tablets were made from the leaves of chaparral or creosote bush, which the American Indians purportedly used for therapeutic benefits. The botanical name for the bush is *cinema ephedra*, and the distributor of the tablets, W. J. Huls, D.O., of Scottsdale, Arizona, used this name for his product.

The District seized 47 bottles of Cinema tablets in the possession of Dr. Huls, on grounds the labeling did not bear adequate directions for use to treat the several conditions for which the product was recommended. The same charge was made in the seizure of a similar preparation distributed by Natures Way Research Products, Mesa, Arizona. This product was also labeled as Cinema tablets, and one bottle remaining from the original lot was seized.

**MINNEAPOLIS DISTRICT** While driving a marked Federal car on a main thoroughfare past the University of Wisconsin, a Minneapolis District FDA inspector was surrounded by a group of demonstrating students when all traffic was halted. In the disturbance that followed, students threw bricks, upset a local police car, vandalized property, and threw a brick through the rear window of the inspector's Government car. The only other damage was to the inspector's nervous sys-

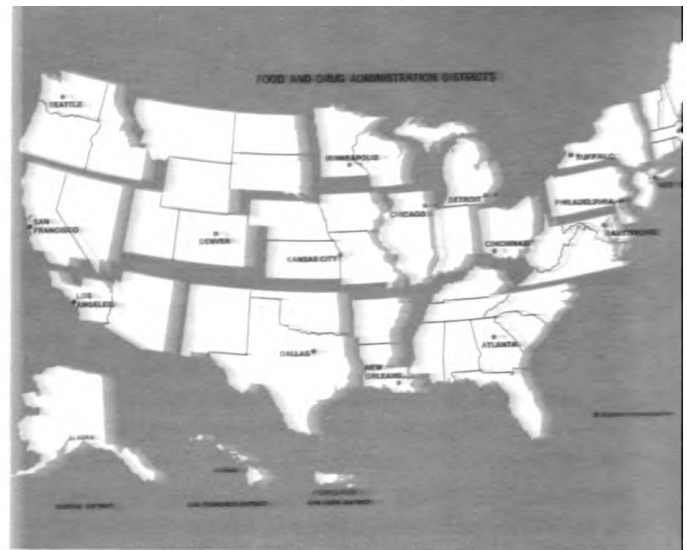
tem. The reported cause of the incident was student resentment at the presence of an electrical products manufacturer's job recruitment team on campus.

**NEW ORLEANS DISTRICT** District detentions of various imports during February included the following products valued at a total of \$78,801: coffee adulterated with bird excreta; canned tomato paste adulterated with metal from the containers; canned pineapple with misleading fill of container; tea adulterated with filth; frozen langostinos containing *E. coli*, coliforms, and coagulase positive staphylococci; and canned tomatoes containing decomposed tomato material.

District seizures included: 35,000 pounds of rodent-contaminated coconut; 20,185 cans of Dr. Pepper diet beverage containing sodium cyclamate; and 1,003 jars of suppositories containing a drug considered to be a new drug without an effective New Drug Application.

**PHILADELPHIA DISTRICT** Jeanne M. Devers, Philadelphia District's consumer specialist, spoke to the biannual meeting of the Republican Women's Club of Norfolk, Virginia, on February 26. The speech concerned "How FDA Protects the Consumer Against Quackery," and was followed by a 45-minute question-and-answer session conducted by Miss Devers. The audience, numbering approximately 150 people, included Republican Party leaders in the Norfolk area.

**SAN FRANCISCO DISTRICT** The District seized 2,500 tons of malting barley in February. The barley was insect infested and stored under insanitary conditions in a Sacramento Valley grain storage facility.



The storage firm has filed a consent decree and the product is to be used for animal feed.

After a warehouse inspection revealed insanitary conditions, the District seized 60 100-pound bags of long grain rice in Fresno, California. The product was rodent gnawed and contaminated with rodent urine, insects, and bird excreta.

**SEATTLE DISTRICT** Seattle District has been helping monitor the disposition of some 750,000 pounds of Michigan coho salmon—contaminated with DDT or condemned as human food for other reasons—being shipped to Alaska to be used as bait for halibut fishing. Monitoring is necessary to assure that the fish remains in nonfood channels. The District checks the seals on the trailerloads arriving from Michigan and checks the transloading and resealing before shipment by ship to Alaska. David Bruce, Alaska State seafood sanitarian, is monitoring receipt of the salmon at the Alaska destination.

#### FDA DISTRICT OFFICES

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

**BALTIMORE** 900 Madison Ave.  
Baltimore, Md. 21201

**BOSTON** 585 Commercial St.  
Boston, Mass. 02109

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

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

**CINCINNATI** 1141 Central Pkwy.  
Cincinnati, Ohio 45202

**DALLAS** 3032 Bryan St.  
Dallas, Tex. 75204

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

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

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

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

**MINNEAPOLIS** 240 Hennepin Ave.  
Minneapolis, Minn. 55401

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

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

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

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

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

#### HEW REGIONAL OFFICES I-X

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

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

**CHARLOTTESVILLE** 220 7th St., N.E.  
Charlottesville, Va. 22901

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

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

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

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

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

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

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

# product safety report

## POISON CONTROL

These reports were submitted by approximately 420 Poison Control Centers throughout the country. They do not represent total ingestions of poisoning incidence in the United States for this period because many cases are advised or treated or both by private physicians or hospitals which generally do not make reports to the Clearinghouse. Although the information also is tabulated according to trade names, this published listing shows only the product categories that are used by the Clearinghouse.

Aspirin and other internal medicines accounted for

20 percent and 48 percent respectively of the total number of reports involving children. The aspirin categories also accounted, in absolute figures, for the greatest number of hospitalizations. However, the corrosive acids and alkalies, combined with the petroleum distillate categories, accounted for a greater ratio of hospitalizations to number of ingestions.

In the age groups five years and over—composed mostly of teenagers and adults—sedatives, tranquilizers, and medicine combinations were most frequently taken and were the cause of the most hospitalizations. This is probably because these are the items most often used in attempts at self-poisoning.

## INGESTION REPORTS SUBMITTED TO THE POISON CONTROL DIVISION

January - June 1969

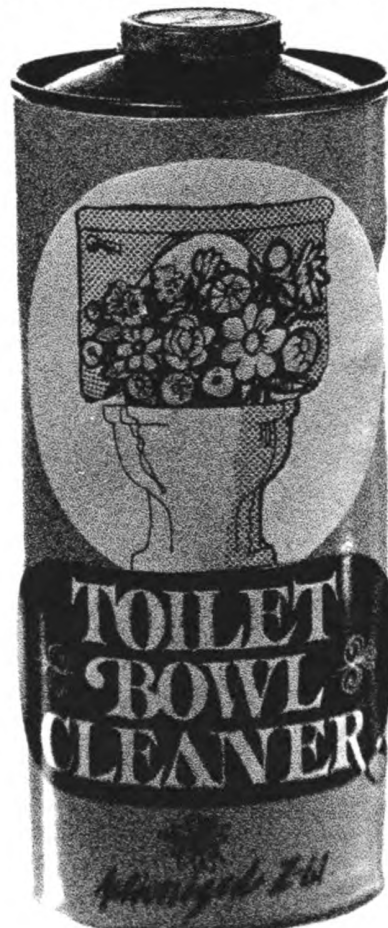
Product	Under 5 Yrs.	5 Yrs. & Over	Unknown Ages	Symptoms Under 5	Symptoms 5 Yrs. & Over	Symptoms Age Unknown	Hospi- talized Under 5	Hospi- talized 5 Yrs. & Over	Hospital- ized Age Unknown	Fatal All Ages
<b>Internal Medicines</b>										
Antihistamines and cold medicines	1,038	224	48	100	84	7	39	42	1	—
Baby aspirin	5,569	272	60	170	15	4	241	12	2	1
Adult aspirin	604	494	37	27	115	11	35	97	2	2
Aspirin, unspecified type	1,408	864	37	51	201	3	84	235	5	2
Miscellaneous analgesics	721	1,162	102	42	411	33	25	314	4	4
Laxatives	460	54	22	45	8	3	12	1	—	—
Barbiturate sedatives	212	1,171	68	52	808	38	41	722	17	14
Nonbarbiturate sedatives	140	1,343	123	25	834	45	10	642	10	10
Cough medicines	587	85	21	91	35	5	33	7	—	—
Internal antibiotics	332	82	24	13	21	5	4	12	2	—
Psychopharmacologic agents	944	2,189	179	198	1,117	57	138	954	20	8
Anticholinergics, antacids	278	74	18	27	31	2	16	20	—	—
Diuretics	175	24	4	13	4	—	9	4	—	—
Iron preparations	210	31	14	26	2	—	51	4	3	—
Vitamins, minerals	2,048	314	96	70	14	4	27	4	—	—
Hormones	807	108	33	21	10	3	15	7	—	—
Cardiovascular medications	268	60	13	27	18	3	20	22	2	1
Amphetamine-type preparations	434	176	29	99	76	12	48	35	1	—
Antidiarrheal agents	193	16	10	26	5	3	22	2	—	2
Vermifuges	77	24	10	7	2	—	1	1	—	—
Miscellaneous internal medicines	1,356	871	150	124	377	37	71	237	9	4
<b>External Medications</b>										
Antiseptic medication	435	144	59	22	31	3	9	12	—	1
Liniments	569	129	44	62	38	9	31	33	1	3
Eye, ear, and nose preparations	172	8	14	12	—	1	5	—	—	—



Product	Under 5 Yrs.	5 Yrs. & Over	Unknown Ages	Symptoms Under 5	Symptoms 5 Yrs. & Over	Symptoms Age Unknown	Hospitalized Under 5	Hospitalized 5 Yrs. & Over	Hospitalized Age Unknown	Fatal All Ages
<b>External Medications</b>										
Ointments	210	8	14	4	—	1	—	—	—	—
Dental preparations	112	27	16	6	7	2	1	—	—	—
Camphor products	122	47	18	24	11	3	27	5	1	—
Medicated lotion and creams	74	14	10	1	4	1	—	—	—	—
Topical baby preparations	303	6	20	16	—	2	—	—	—	—
Miscellaneous external medicines	484	95	55	46	25	5	11	11	—	1
<b>Household Products</b>										
Household bleach	953	172	82	84	32	8	22	17	—	—
Household disinfectants and deodorizers	864	66	97	71	12	6	24	6	—	—
Corrosive acids and alkalines	800	142	115	249	74	29	140	29	2	—
Solid polish or wax	40	1	5	1	—	—	2	—	—	—
Drycleaning fluids, spot removers	79	39	21	16	18	3	4	8	—	—
Soaps, detergents, cleaners	1,629	204	201	152	58	31	23	12	1	—
Shoe preparations	139	13	12	12	1	1	3	—	—	—
Liquid polish or wax	579	35	45	59	4	4	63	5	—	1
Miscellaneous household products	217	29	44	7	7	3	2	—	—	—
<b>Petroleum Distillates</b>										
Kerosene	321	25	15	104	6	2	118	6	1	—
Lighter fluids	495	50	34	87	9	7	53	3	1	—
Naphtha	3	—	2	1	—	1	—	—	—	—
Gasoline	333	180	54	74	45	12	55	9	—	—
Petroleum solvents and cleaners	128	12	16	21	5	3	17	4	1	—
Miscellaneous petroleum products	418	47	39	36	5	4	27	1	—	1
<b>Cosmetics</b>										
Fingernail preparations	352	19	19	22	—	1	2	1	—	—
Perfume, cologne, toilet water	1,034	27	49	47	—	1	7	—	—	—
Personal deodorants	100	15	8	8	5	1	1	—	—	1
Hair preparations, except shampoo	296	30	34	16	4	5	3	—	—	—
Cosmetic lotions and creams	475	22	56	29	1	2	3	1	—	—
Hair shampoo	107	10	9	7	1	1	—	—	—	—
Miscellaneous cosmetics	251	10	20	20	6	1	2	2	—	—



Product	Under 5 Yrs.	5 Yrs. & Over	Unknown Ages	Symptoms Under 5	Symptoms 5 Yrs. & Over	Symptoms Age Unknown	Hospi- talized Under 5	Hospi- talized 5 Yrs. & Over	Hospital- ized Age Unknown	Fatal All Ages
<b>Pesticides</b>										
Insecticides	825	276	219	65	93	57	46	53	3	8
Rodenticides	502	76	50	14	20	5	54	16	1	4
Fungicides	33	17	9	2	3	3	3	—	—	—
Herbicides	64	36	56	12	12	19	3	4	—	2
Moth balls	356	25	33	7	1	2	9	2	—	—
Animal repellents	36	19	26	6	9	2	—	—	—	—
Insect repellents	57	15	12	7	5	1	1	1	—	—
<b>Other Products</b>										
Carbon monoxide	18	77	24	10	56	11	—	28	1	1
Gases, vapors, fumes	14	112	95	4	71	38	2	13	—	—
Mushrooms, toadstools	176	19	19	5	—	—	3	1	—	—
Plants	848	284	188	49	69	19	11	17	—	—
Household product combinations	102	47	25	14	26	7	2	10	—	3
Medicine combinations	588	2,332	136	84	1,340	56	72	1,141	19	12
Reference Category	214	41	29	16	6	4	7	8	—	—
Manufacturers	3	—	—	—	—	—	—	—	—	—
Miscellaneous products	499	134	110	29	29	14	9	6	—	—
Tobacco	102	4	5	8	2	—	—	17	—	—
Alcoholic beverages	31	55	5	14	37	2	7	17	—	—
Children's paints, crayons, modeling clay	241	24	12	3	1	2	1	—	—	—
Venom-snake or spider	81	252	139	28	83	50	—	5	—	—
Ink	182	69	21	12	8	—	—	1	—	—
Matches	176	6	11	3	—	1	—	—	—	—
Fertilizers, plant foods	238	53	37	12	9	4	5	—	—	—
Chemicals	336	251	145	29	58	22	13	17	1	3
Paint	455	67	54	21	14	15	4	2	—	—
Turpentine	374	37	14	58	7	—	44	4	—	—
Solvents and thinners	478	106	87	73	36	22	44	17	1	3
Oil paints, stains, and preservatives	125	118	21	5	5	4	3	1	1	—
Glues and adhesives	652	74	62	52	19	4	9	3	—	—
Unknown	237	479	46	23	212	14	15	235	9	7
Veterinary products	190	15	19	10	3	—	2	2	—	—
Pesticide combinations	9	11	5	1	5	2	2	2	—	—
<b>Total All Cases Reported</b>	<b>38,197</b>	<b>16,295</b>	<b>4,039</b>	<b>3,246</b>	<b>6,836</b>	<b>808</b>	<b>1,968</b>	<b>5,145</b>	<b>122</b>	<b>99</b>



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# state actions

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**Wisconsin DDT Ban** Warren P. Knowles, Governor of Wisconsin, has signed into law a bill which bans the sale, distribution, or use of DDT and its isomers in the State. The law, signed February 13, provides for emergency use of DDT only in the event of a serious epidemic disease among humans, animals, or plants, and when DDT is the only known effective means of control. The new law is now in effect.

Wisconsin has also updated its Hazardous Substances Act to cover toys and other articles intended for use by children. The new amendments also give the State's Department of Agriculture authority to ban the sale of certain hazardous substances in addition to regulation of cautionary labeling provisions.

**Legislative Action** A bill to curtail the use of DDT in Kentucky passed the Kentucky State Senate by a vote of 35-0 and has gone to the House. Sponsors of the legislation estimate it would reduce by 75 percent the amount of DDT introduced into the State's environment. It would outlaw the use of DDT on crops and livestock. However, DDT would still be available for control of household pests, subterranean termites, bats, rats, mice, or any other use for which the Director of the Kentucky Agriculture Experiment Station "finds there is no safe substitute."

**Oregon Pesticide Cancellations** Virgil Hiatt, chief chemist with the Oregon Department of Agriculture, said Oregon will follow the same procedure of cancellation as that announced by the U.S. Department of Agriculture concerning cancellation of pesticide registrations of five more mercury compounds used in treatment of seeds. The five are ethylmercury acetate; ethylmercury chloride; n-(ethylmercury)P-tolu-

enesulfonanilide; methylmercury 2, 3-dihydroxy propyl mercaptide and methylmercury 8-quinolinolate.

Earlier the USDA cancelled the registration for another mercurial seed treatment, cyano (methylmercury) guanidine. Both the Federal Government and the State are suggesting that any of the above chemicals on hand be used and not dumped and that treated seed be planted. They are encouraging use of substitute materials for seed treatment. Some of the materials mentioned are captan, PCNB, thiram, ferbam, and phenylmercuric acetate.

**Hazardous Substances Law** The State of Tennessee, using the Federal Hazardous Substances Act as a guide, has enacted legislation which includes the provisions of the Child Safety Act and the Toy Safety Act as well as the basic provisions of the Hazardous Substances Act. The new State Act was passed last January 29.

**Lead in Pottery** *Good Housekeeping Magazine* carried an article last November about the lead poisoning of a family. The poisoning was traced to a ceramic pitcher purchased in Mexico.

Officials of the Ohio Department of Agriculture saw the article and, in December 1969, secured samples of similar pottery from a Cincinnati importer. Lab analysis of the clay mugs and bowls revealed lead in amounts ranging from 0.16 micrograms to 19.8 micrograms per 1 milliliter of acetic acid, which was used as the leaching agent.

On January 14, the Ohio Department of Agriculture advised known Ohio importers that such articles should not be sold as food containers.

**Damaged Foods Destroyed** Fire in a railroad car loaded with liquid

and powdered infant food formula resulted in water, smoke, and extreme heat damage to the product and containers. The fire occurred inside the car in a Detroit railroad yard. After a prolonged delay, the car was returned to the processing plant in Illinois. Upon investigation, the entire shipment, valued at \$17,000, was ordered destroyed by the Illinois Department of Public Health—Division of Food and Drugs Inspector Richard L. Peterson and Division of Milk Control Sanitarian Lewis W. Schultz. The damaged goods were buried in a sanitary landfill disposal area.

**Commissioning** Leland Bull, Secretary of the Pennsylvania Department of Agriculture, presented commissions as Food and Drug Administration Officers to seven inspectors in the Department's Feed and Fertilizer Division of the Bureau of Foods and Chemistry on March 2. Secretary Bull called the commissioning "an example of State/Federal cooperation which offers consumer protection at a cost reduction."

The commissions authorize the inspectors to assume certain duties formerly performed by FDA inspectors in Pennsylvania. Attending the ceremonies were Kelvin Keith, deputy director, Buffalo District; Weems L. Clevenger, regional food and drug director; Ralph Bernstein, associate regional food and drug director; and Irwin B. Berch, director, Philadelphia District.

**Salvage Disposal** Under an agreement with FDA's Boston District, the Commonwealth of Massachusetts will supervise the reconditioning or destruction of 36 truckloads of merchandise salvaged from a large warehouse fire that occurred in western New York. The merchandise includes foods, drugs, and cosmetics.



# 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 37 seizure actions to remove from the consumer market products charged to be violative were reported in March. These included 18 seizures of foods: 17 involved charges concerning contamination, and 1 involved charges

concerning economic violations. Other seizures included 1 of vitamins, 17 of drugs (including 1 of veterinary and medicated feed), and 1 of hazardous substance.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>FOOD / Contamination, Spoilage, Insanitary Handling</b>		
Chili peppers (Japanese)/Los Angeles, Calif. 1/2/70	Arizona Picos Packing Co./Los Angeles, Calif. (D)	Held under insanitary conditions; rodent contaminated.
Coconut, desiccated/New Orleans, La. 2/25/70	A. J. Warehouse, Inc./New Orleans, La. (D)	"
Cornmeal, yellow/Baltimore, Md. 2/3/70	Western Maryland Railway Co./Baltimore, Md.	"
Flour, powdered sugar/Washington Court House, Ohio 2/24/70	Central Grocery Co./Washington Court House, Ohio (D)	"
Hash brown potatoes/Hayward, Calif. 1/22/70	North Pacific Cannery & Packers, Inc./Portland, Oreg. (S)	Prepared and packed under insanitary conditions; high total bacterial count.
I.Q.P. strawberries/Columbus, Ohio 3/9/70	International Frozen Foods/Laredo, Tex. (S)	Rodent contaminated.
Malting barley/Woodland, Calif. 2/12/70	Adams, Schwab & Adams/Woodland, Calif. (D)	Held under insanitary conditions; insect and rodent contaminated.
Peanuts/Toledo, Ohio 2/16/70	Toledo Terminal Warehouse/Toledo, Ohio (D)	Held under insanitary conditions; rodent contaminated.
Pecan halves/Minneapolis, Minn. 2/11/70	SNA Nut Co./Chicago, Ill. (M,S)	Prepared and packed under insanitary conditions; E. coli.
pieces/St. Paul, Minn. 2/11/70	"	"
Milwaukee, Wis. 2/17/70	Eufaula Pecan Co./Eufaula, Ala. (M,S)	"
Rice, long grain/Fresno, Calif. 2/20/70	Marbo Quality Foods, Inc./Fresno, Calif. (D)	Held under insanitary conditions; rodent, insect, and bird contaminated.
Spaghetti, cut/Wichita, Kans. 2/20/70	Ranney Davis Mercantile Co./Wichita, Kans. (D)	Held under insanitary conditions; insects.
Tootsie Rolls/Fresno, Calif. 3/6/70	Insanitary conditions in transit,/Houston, Tex.— Fresno, Calif.	" ; moldy, insects.
Tuna fish, white/Cambridge, Mass. 3/2/70	Bumble Bee Seafoods/Astoria, Oreg. (P,S)	Prepared and packed under insanitary conditions.
Walnut(s)/Fort Smith, Ark. 2/18/70	Simco Produce Co./Fort Smith, Ark. (D)	Held under insanitary conditions; rodents.
pieces/Milwaukee, Wis. 2/17/70	Guerra Nut Shelling Co./Hollister, Calif. (P,S)	Prepared and packed under insanitary conditions; E. coli.

## Economic Violations

Tuna, chunk/Miami, Fla. 2/24/70	Star-Kist Foods, Inc./Terminal Island, Calif. (M,S)	Fails to conform to standard of identity for canned tuna.
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## Vitamins

B complex vitamins w/minerals/Oakland, Calif. 3/11/70	Lura-Glo Products, Inc./Oakland, Calif. (D)	Contain folic acid and potassium iodide, food additives not in conformity with regulations; "high potency" label is misleading; lack full dietary information.
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PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>DRUGS / Human Use</b>		
Asper-Sleep tablets/Melrose Park, Ill. 2/4/70	Yonkers Laboratories, Inc./Yonkers, N.Y. (M,S)	New drug not approved for safety and efficacy.
Calcium chloride injection/Detroit, Mich. 2/20/70	Dr. Robert Kallaman/Detroit, Mich. (D)	Not packaged in single-dose containers as required in NF.
Chorionic gonadotropin/El Paso, Tex. 1/30/70	Interstate Pharmaceuticals/San Gabriel, Calif. (M, S)	Below labeled strength.
Firm-A-Form Mini-Kit/Chicago, Ill. 2/2/70	Firm-A-Form, Inc./Fort Lauderdale, Fla. (M, S)	New drug not approved for safety and efficacy.
First Aid cream/New York, N.Y. 1/2/70	Suburban Sales Co./Philadelphia, Pa. (S)	"
Guaicresodide/Kansas City, Kans. 3/17/70	Henry C. Haist Co., Inc./Kansas City, Mo. (M,S)	Not prepared and packed in conformity with good manufacturing practice.
Hairseptic/Fort Wayne, Ind. 2/26/70	Ohio Steakette & Barbeque of Dayton, Inc., d/b/a Aristocrat Hairseptic Co./Columbus, Ohio (M,S)	New drug not approved for safety and efficacy.
Liver injection/Detroit, Mich. 3/6/70	C. F. Dodenhoff, M.D./Detroit, Mich. (D)	"
Lypo-Bex-C/Minneapolis, Minn. 2/13/70	Glogau & Co., Inc./Chicago, Ill. (M,S)	Not packaged as prescribed in NF. Not prepared and packed in conformity with good manufacturing practice; below labeled strength in vitamin B-12.
Margane tablets/Minneapolis, Minn. 2/13/70	Northrup Pharmaceutical Co./Minneapolis, Minn. (D)	Below labeled strength in aluminum aspirin.
Neurobexin, Neuralvitis, and Neurobion/Santurce, P.R. 2/9/70	Dianovin Pharmaceuticals, Inc./Santurce, P.R. (D)	Below labeled strength.
Niripase tablets/ Minneapolis, Minn. 2/24/70	Strong Cobb Arner, Inc./Cleveland, Ohio (M,S)	Below labeled strength in methamphetamine hydro- chloride.
Oxytetracycline HCl/Detroit, Mich. 3/6/70	Davis-Edwards Pharmacal Corp./Danbury, Conn. (M,S)	Uncertified.
Sulfapyridine tablets/Louisville, Ky. 3/10/70	Superior Pharmacal Co./Dayton, Ohio (M,S)	Below USP standard for quality; fail disintegration test for enteric-coated tablets.
Xerac alcohol acne gel/Melrose Park, Ill. 2/4/70	Person & Covey/Glendale, Calif. (M,S)	New drug not approved for safety and efficacy.
<b>Veterinary / Medicated Feed</b>		
Enditch tablets, Prednameen edible tablets, green washable ointment for dogs and cats/Greenwich, Conn. 2/16/70	Columbia Pharmaceutical Co./Freeport, N.Y., and Durel Pharmaceutical, Inc./Mount Vernon, N.Y. (M,S)	New drugs not approved for safety and efficacy.
<b>HAZARDOUS SUBSTANCES</b>		
Weldwood contact cement, Big Stick construction adhesive/Kalamazoo, Mich. 1/20/70	U. S. Plywood-Protection Products Div./Kalamazoo, Mich. (D)	Lack 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.

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

March 6, 1970: American Image Corp., New York, N.Y. Advertising and sale by mail of weight reduction plan entitled "Crash

Diet" represented as enabling dieter to "Eat your fill" while losing up to five pounds overnight.

## NOTICES OF JUDGMENT on Seizure Actions

### FOOD / Poisonous and Deleterious Substances

#### Blood meal, animal feed, at Lynn Center, S. Dist. Ill.

Charged 10-20-69: when shipped by Midwest Commodities, Inc., Milwaukee, Mich., the article contained the poisonous and deleterious substance *Salmonella* bacteria; 402(a)(1). Default decree ordered destruction. (1)

### FOOD / Contamination, Spoilage, Insanitary Handling

#### Alcoholic beverages, assorted, at Biloxi, S. Dist. Miss.

Charged 10-9-69: while held by Desert Package Liquor Store, Biloxi, Miss., the articles were held under insanitary conditions in polluted floodwaters; 402(a)(4). Default decree ordered destruction. (2)

#### Clams, frozen, at Atlanta, N. Dist. Ga.

Charged 9-17-69: when shipped by Howard Johnson's Meat Commissary, Queens Village, N.Y., the article contained decomposed clams; 402(a)(3). Default decree ordered destruction. (3)

#### Flour, at Los Angeles, C. Dist. Calif.

Charged 9-17-69: while held by California Grocery Trading Co., Los Angeles, Calif., who repacked the article into 100-lb. bags, the article contained insect and rodent filth; 402(a)(3). Default decree ordered destruction. (4)

#### Malt, at Carolina, Dist. P.R.

Charged 9-17-69: while held by Antilles Brewing Co., Carolina, P.R., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (5)

#### Nutmeg, at Detroit, E. Dist. Mich.

Charged 10-22-69: when shipped by Murbas Trading Co., New York, N.Y., the article contained insect filth and moldy, decomposed nutmegs; 402(a)(3). Consent decree authorized release to shipper for salvaging. (6)

#### Peanut granules, at Detroit, E. Dist. Mich.

Charged 10-22-69: when shipped by Aster Nut Products, Evansville, Ind., the article contained insect filth and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (7)

#### Pepper, black, at Gretna, E. Dist. La.

Charged 9-23-69: while held by Zatarain's, Inc., Gretna, La., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (8)

#### Potatoes, stuffed, frozen, at St. Louis, E. Dist. Mo.

Charged 8-7-69: when shipped by Lafayette Refrigerated Services, Inc., Lafayette, Ind., the article, labeled in part "Holloway House, Inc. Div. J. R. Thompson Co. Chicago, Ill. . . . Stuffed Baked Potatoes topped with cheddar cheese," contained excessive coagulase positive staphylococci and a high bacterial count and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (9)

#### Shrimp, breaded, frozen, at Los Angeles, C. Dist. Calif.

Charged 9-11-69: while held by Coral Queen Frozen Foods, Inc., Los Angeles, Calif., the article contained bacterial filth and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (10)

#### Walnuts, black, Blue Ribbon, at Detroit, E. Dist. Mich.

Charged 4-28-69: when shipped by Continental Nut Co., Chico, Calif., the article contained E. coli; 402(a)(3). Consent decree authorized release to A. J. Bellish Co., for salvaging. (11)

#### Walnuts, black, Blue Ribbon, at Springfield, W. Dist. Mo.

Charged 7-24-69: when shipped by Continental Nut Co., Chico, Calif., the article contained E. coli; 402(a)(3). Consent decree authorized release to shipper for salvaging. (12)

#### Wheat, at Minneapolis, Dist. Minn.

Charged 11-25-69: when shipped by Maddock Farmers Grain Co., Maddock, N. Dak., the article contained rodent filth; 402(a)(3). Consent decree authorized release to shipper for reconditioning. (13)

### FOOD ADDITIVES

#### Chub fish, smoked, at Detroit, E. Dist. Mich.

Charged 10-22-69: when shipped by Vita Food Products, Inc., Chicago, Ill., the article contained the nonconforming food additives DDT and DDE; 402(a)(2)(C). Default decree ordered destruction. (14)

#### Meat additive, "B.T.", at Portland, Dist. Oreg.

Charged on or about 8-26-69: when shipped by Tender Treat Co., Inc., Spokane, Wash., the article contained the nonconforming food additives sodium bisulfite and sodium sulfite—402(a)(2)(C); and the labeling contained false and misleading representations that the article was suitable and appropriate for use in meat products—403(a). Default decree ordered destruction. (15)

### DRUGS / Human Use

#### Acetaminophen suppositories, at Hialeah, S. Dist. Fla.

Charged 8-12-69: when shipped by Ario Interamerican Corp. of Puerto Rico, Hato Rey, P.R., the labeling of the article, labeled in part

"Suppositories Duralgina . . . Acetaminophen . . . Distributed by Kessel Laboratories, Inc., Miami, Fla.," failed to bear adequate directions for use; 502(f)(1). Default decree ordered destruction. (16)

#### Chlorpheniramine maleate timed-disintegration tablets, at Norfolk, E. Dist. Va.

Charged 1-27-69: when shipped by the American Tablet & Capsule Co., Inc., Brooklyn, N.Y., the labeling of the article, labeled in part "Timed Disintegration Tablets Norhist-8 . . . Chlorpheniramine Maleate 8 mg. U.S.P. Distributed by Norfolk Drug Corp., Norfolk, Virginia," was false and misleading, since the article was not recognized in the United States Pharmacopeia as represented—502(a); and, while held for sale, the article's quality was deficient because of the failure of the tablets of the article to disintegrate completely—501(c). Default decree ordered destruction. (17)

#### First Aid for Headaches acetaminophen tablets, N.F., at Philadelphia, E. Dist. Pa.

Charged 7-30-69: while held by Chex Co., Philadelphia, Pa., who manufactured the article from acetaminophen shipped in interstate commerce, the article's display carton contained false and misleading statements that the article also contained salicylamide, acetophenetidin, and caffeine, when the article did not contain such additional ingredients; and its labeling lacked adequate warnings against administration to children under 3 years of age and against use for more than 10 days unless directed by a physician; 502(a), 502(f)(2). Default decree ordered destruction. (18)

#### Iodine tannic acid complex solution and horse chestnut combination drops, at Hialeah, S. Dist. Fla.

Charged 8-12-69: while held for sale after manufacture in Florida from some ingredients shipped in interstate commerce, the article, labeled in part "Yodarsol . . . Iodine-Tannic Acid Complex in a sorbitol-sucrose base . . . Distributed by Kessel Laboratories, Inc., Coral Gables, Florida," differed in strength from its purported strength, and lacked adequate directions for use—502(f)(1), 501(c); and the article, labeled in part "Fluxine Drops . . . Horse chestnut extract, Black Haw Bark extract, Nux Vomica tincture . . . Manufactured by Roger Pharmacal Co., Miami 1, Florida" had bottle and carton labeling which contained false and misleading claims for uncomplicated and minor engorgement of veins, uncomplicated hemorrhoids, and painful menstruation; and its label lacked the quantity or proportion of strychnine in the nux vomica of the article—502(a), 502(e)(1)(A)(ii). Default decree ordered destruction. (19)

#### Kay-Eze analgesic capsules, at Jackson, S. Dist. Miss.

Charged 4-11-69: while held by Kay-Cee Products, Inc., Jackson, Miss., the dealer's labeling contained false and misleading claims for the treatment of arthritis and pain and swelling due to arthritis; 502(a). Consent decree authorized release of the article to dealer for relabeling and permanently enjoined the dealer, its president, Henry N. Brown, and the proposed purchaser of the dealer's business, the Better Business and Industrial Development Corp., Jackson, Miss., from the use of literature or labeling in connection with the promotion and sale of the article representing the article as an adequate and effective treatment for arthritis. (20)

#### Precta-Biotic rectal ointment, at Coral Gables, S. Dist. Fla.

Charged 7-11-69: while held by Barred Research Labs., Coral Gables, Fla., who manufactured the article from sulfathiazole and hydrocortisone acetate shipped in interstate commerce, the name and labeling was false and misleading, since the article contained no antibiotic ingredient, and the labeling lacked adequate directions and did not comply with the Rx drug exemption requirement for disclosure of information; 502(a), 502(f)(1). Default decree ordered destruction. (21)

#### Propoxyphene combination tablets, at Plainville, Long Island, E. Dist. N.Y.

Charged 11-18-68: when shipped by Milan Pharmaceuticals, Inc., Morgan-town, W. Va., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (22)

#### Stramonium combination cigarettes for asthma paroxysms, at Chattanooga, E. Dist. Tenn.

Charged 8-26-69: when shipped by Calotabs Co., Inc., Daytona Beach, Fla., the article, labeled in part "Blosser's Cigarettes . . . The Blosser Cigarette Company Sole Distributors, Daytona Beach, Florida," was a prescription drug, and it failed to bear the prescription legend; 503(b)(4). Default decree ordered destruction. (23)

#### Trihista-Phen, Tri-Histrix, and Tri-Histin Expectorant antihistamine liquids, Dizymes enzyme capsules, and Estrosan estrogen tablets, at Santa Barbara and Goleta, C. Dist. Calif.

Charged 8-27-69: while held by Recsei Laboratories (who had packed the articles) at Santa Barbara, Calif., the antihistamine liquids lacked warning statements concerning drowsiness—502(f)(2); the Tri-Histin Expectorant antihistamine liquid also lacked warning statements concerning use of phenylephrine and phenylpropanolamine HCl by individuals with high blood pressure, heart disease, diabetes, or thyroid disease—502(f)(2); Tri-Histin antihistamine liquids lacked adequate directions for use for "allergic conditions"—502(f)(1); the Trihista-Phen antihistamine liquid differed from its labeled strength, since it contained approximately 20 percent excess of glyceryl guaiacolate, methapyrilene HCl, pyrilamine maleate, and phenylpropanolamine HCl—501(c); and the 10-mcg. Estrosan tablets had labeling which contained false and misleading claims for hypercholesterolemia, atherosclerosis, post-menopausal syndromes and acne, and lacked the established name of the active ingredient of the article—502(a), 502(e)(1)(A)(i). While held for sale at Goleta, Calif., after having been packed by Recsei Laboratories of Santa Barbara, Calif., Dizymes enzyme capsules had labeling which



contained false and misleading claims for trauma; Trihista-Phen and Tri-Histin Expectorant antihistamine liquids were charged as above—502(f)(2), 501(c); the 10-mcg. Estrospan tablets had the false and misleading labeling charged above and the 2.5-mcg. Estrospan tablets had labeling which contained false and misleading claims for angina pectoris as well as hypercholesterolemia, atherosclerosis, post-menopausal syndromes and acne—502(a). Default decree ordered destruction. (24)

**Ultra-Sept Tine germicidal solution, Ultra-Sept Eye Klean eyewash, and Ultra-Sept oil,** at Houston, S. Dist. Tex.  
Charged 7-30-69: when shipped by Golden State Supply Co., Los Angeles, Calif., the labeling of the articles lacked adequate directions for use, adequate warnings, and the established name of each active ingredient, and the labeling of the Ultra-Sept oil contained false and misleading therapeutic claims for sunburn, insect bites, and bacterial skin infection; 502(a), 502(f)(1), 502(f)(2), 502(e)(1)(A)(II). Default decree ordered destruction. (25)

**Vanamil liquid antacid,** at Kansas City, W. Dist. Mo.  
Charged 10-28-69: when shipped by Vicks Chemical Co., Div. of Richardson-Merrell, Inc., Philadelphia, Pa., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (26)

**Yohimbine-testosterone combination capsules,** at Hialeah, S. Dist. Fla.  
Charged 8-12-69: when shipped by Lit Drug Co., Newark, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (27)

#### DRUGS / Veterinary

**Mastitis antibiotic syringes and calcium-dextrose injectable,** at Jacksonville, M. Dist. Fla.  
Charged 5-26-69: while held for sale, the quality of the syringes fell below purported quality and the label of the syringes lacked an accurate statement of the quantity of contents, since they were approximately 7 percent deficient, they showed evidence of leakage from the plunger and only approximately 87 percent of the antibiotic could be extruded through the syringe—501(c), 502(b)(2); and when shipped by Performance Products, Inc., St. Louis, Mo., the calcium-dextrose injectable, labeled in part "Calcium-Dextrose with Magnesium-Phosphorus," Mfd. for Southeastern Laboratories, Inc., Jacksonville 3, Florida, lacked adequate directions for use and was not exempted therefrom, since it was not safe for its intended intraperitoneal administration in horses, except under veterinary supervision, and the labeling lacked the veterinary legend restricting its sale—502(f)(1). Default decree ordered destruction. (28)

**Yellow Marker sterile veterinary solution,** at Hialeah, S. Dist. Fla.  
Charged 12-19-69: when shipped by Curtis Labs., Inc., Kansas City, Mo., and while held by Professional Veterinary Services, Inc., Hialeah, Fla., the article was a new animal drug without an effective approved New Animal Drug Application, the labeling lacked adequate directions and warnings and the article was an imitation of another drug, D.N.P. Disophenol Parenteral; 501(a)(5), 502(f)(1), 502(f)(2), 502(l)(2). Default decree ordered destruction. (29)

#### MEDICAL DEVICES

**Life-guard Oxygen-resuscitator mask,** at Miami, S. Dist. Fla.  
Charged 11-25-69: when shipped by Life Aid Products, Ltd., Toronto, Ontario, Canada, the labeling which represented that the article contained 15 to 20 minutes of medical oxygen for emergency first aid was false and misleading, since the amount of available oxygen was not sufficient to maintain a proper supply of oxygen for 15 to 20 minutes, the labeling lacked adequate directions for the intended uses, and lacked adequate warnings; 502(a), 502(f)(1), 502(f)(2). Default decree ordered destruction. (30)

**Respirator,** at Jackson, S. Dist. Miss.  
Charged 7-7-69: when shipped by Crown Products Co., Cleveland, Ohio, the article, labeled in part "Res-Q-Aire Emergency Respirator," Machsa, Inc., Cleveland, Ohio 44101, bore the name "Res-Q-Aire" and statements on the carton label and attached card which were false and misleading as to the adequacy and effectiveness of the article as to means of resuscitation; the labeling lacked adequate directions for use, and such could not be written, since the article was neither effective nor safe for its intended purpose; the labeling lacked warnings against use involving obstructions, aspirated objects and dentures, and involving infants or children where the volume of air would be excessive; and the article was dangerous to health when used as directed by its labeling; 502(a), 502(f)(1), 502(f)(2), 502(j). Default decree ordered destruction. (31)

#### PROPHYLACTICS

**Rubber prophylactics, Aztec,** at Fort Worth, N. Dist. Tex.  
Charged 9-5-69: when shipped by Barnett's, Inc., Charlotte, N.C., the article's quality was deficient and the labeling was false and misleading, since the article contained holes; 501(c), 502(a). Default decree ordered destruction. (32)

#### COSMETICS / Beauty Products

**Clayton's Scalp Good hair preparation, Perfect Four bergamot hair conditioner, Indian Maid Beauty Sage and Sulphur dandruff compounds, and Cherokee Sage and Sulphur dandruff compound,** at Clayton, E. Dist. N.C.  
Charged 8-6-69: while held by Woodrow Russell Beard, t/a Clayton Products Manufacturing Co., Clayton, N.C., who manufactured the articles from active ingredients shipped in interstate commerce, the labeling of the Scalp Good preparation and Perfect Four bergamot conditioner contained false and misleading claims for the treatment and prevention of hair and scalp problems—602(a); the labeling of the Indian Maid Beauty compound (green and white labeled article) and the labeling of the Cherokee compound were false and misleading, since the articles did not contain an amount of sulphur which was of significant

value for the articles' intended purposes, the labeling contained false and misleading claims for treatment of scalp problems, and the labeling lacked adequate warnings to discontinue use and consult a physician if undue skin irritation develops or increases—502(a), 502(f)(2); and the labeling of the Indian Maid Beauty compound (red and yellow labeled article) was false and misleading, since the article did not contain an amount of sulphur which was of significant value for the article's intended purpose, and the labeling lacked adequate directions for use and warnings to discontinue use and consult a physician if undue skin irritation develops or increases—502(a), 502(f)(1), 502(f)(2). Consent decree authorized release to dealer for relabeling. (33)

#### HAZARDOUS SUBSTANCES

**Bondrite contact cements and a cement solvent,** at Lemont, N. Dist. Ill.  
Charged 7-8-69: when shipped by UBS Chemical Co., Div. of A. E. Staley Manufacturing Co., Cambridge, Mass., the cement solvent, labeled in part "Conolite Solvent for Contact Cement," Conolite Division, Woodall Industries Inc., Carpenterville, Illinois, and the contact cements were extremely flammable substances, and lacked a number of the required conspicuous label statements—2(p)(1) [except the solvent], E, F & I; and the labels of the cements also contained the statement, "Although this adhesive is no more hazardous than dry cleaning fluids or gasoline," that negated and disclaimed the required statements—2(p)(1). Default decree ordered destruction. (34)

**Cherry Bombs, M-80 firecrackers, and Super Bulldog salutes,** at Canby, Dist. Ore.  
Charged 5-9-69: when shipped by New Jersey Fireworks Manufacturing Co., Inc., Vineland, N.J., the articles were banned hazardous substances, since they were toys which were flammable solids and generated pressure through explosion when ignited; 2(q)(1)(A). Consent decree authorized release to R. M. Weygandt, t/a Western Fireworks Co., Canby, Ore., for relabeling and disposal as pest control bombs. (35)

**Con-Bond contact cement,** at Denver, Dist. Colo.  
Charged 6-13-69: when shipped by Columbia Cement Co., Inc., Brooklyn, N.Y., the article was extremely flammable and it lacked a number of the required conspicuous label statements; 2(p)(1)(E, F & I). Default decree ordered destruction. (36)

**Vinyl-Tap-Keto Kit,** at Detroit, E. Dist. Mich.  
Charged 4-16-69: while held by King Chemical & Equipment Co., Detroit, Mich., after having manufactured the article from lacetene shipped in interstate commerce, the article was flammable, and presented a special hazard by reason of its petroleum distillate content, and lacked required conspicuous label statements; the signal word "Danger" and the statement of hazard "Harmful or Fatal if Swallowed" were inconspicuous, since they did appear on the main panel of the label, and the cautionary statements on the label were inconspicuous, since they did not appear in the required type size and lacked adequate contrast; 2(p)(1)(E), 2(p)(2), 3(b). Default decree ordered destruction. (37)

#### NOTICES OF JUDGMENT on Criminal Actions

#### FOOD

**Ancher Sea Foods Corp.,** Los Angeles, C. Dist. Calif.  
Charged 8-8-69: while held for sale, scallops were exposed to and contaminated with bacterial filth, and were held, prepared, and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea; fine. (38)

#### NOTICES OF JUDGMENT on Injunction Actions

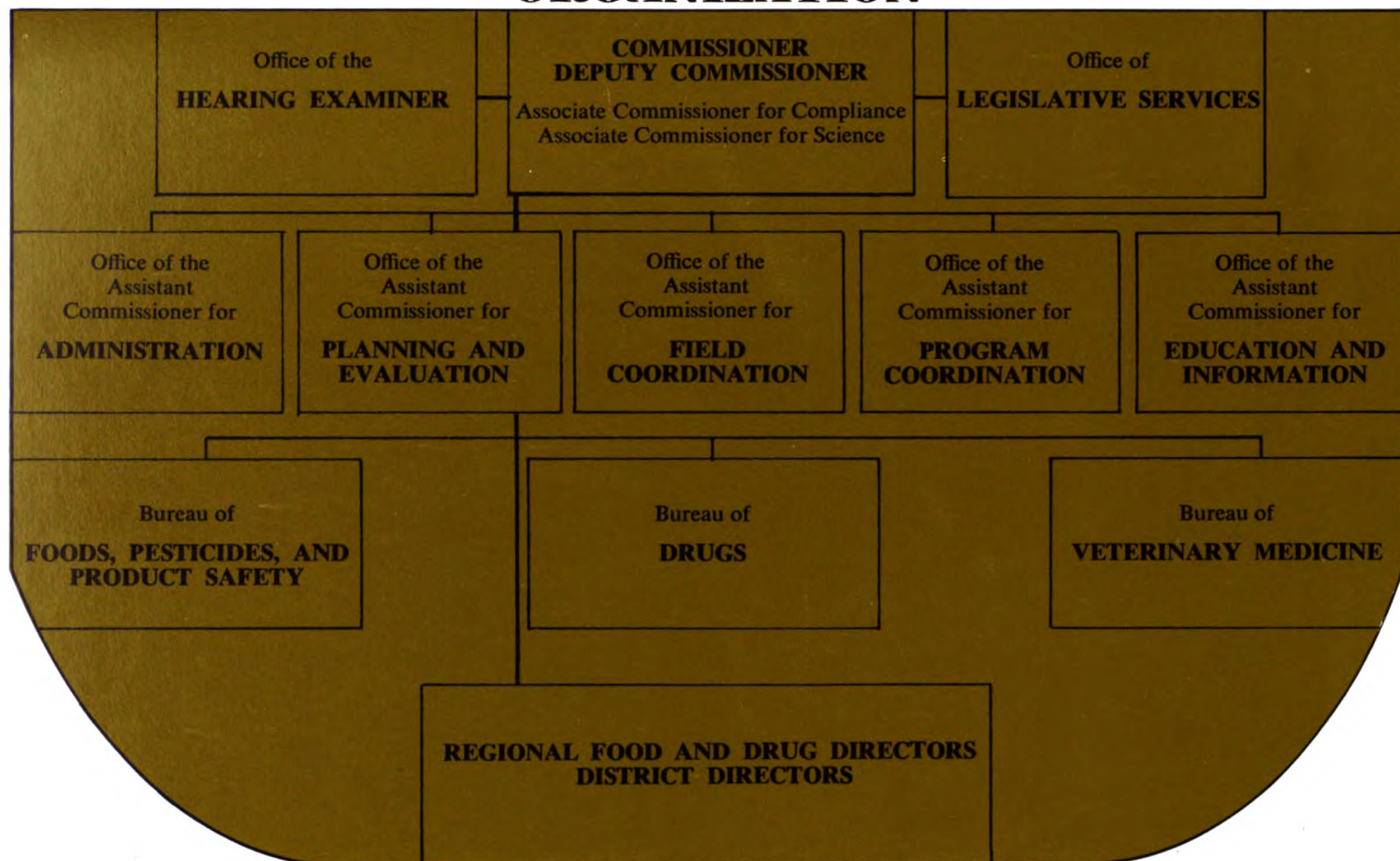
**Acme Smoked Fish Corp., Acree Sales Co. (a partnership), Rubin Caslow, corporation vice president and a partner, and Joseph Brownstein, corporation treasurer and a partner,** Brooklyn, E. Dist. N.Y.  
Charged 3-6-67 in complaint for injunction: that the defendants were engaged in receiving fish from sources outside the State of New York and in preparing, smoking, packing, holding, and distributing such fish for human consumption; that when distributed, the fish contained the added poisonous and deleterious substance *Salmonella* micro-organisms, and had been prepared, packed, and held at the defendants' plant at Brooklyn, N.Y., under insanitary conditions; 402(a)(1), 402(a)(4). Consent decree of permanent injunction enjoined the defendants against the interstate shipment of such violative fish and against the processing and distribution of fish held for sale after shipment in interstate commerce unless and until the defendants' plant was cleaned, specified insanitary conditions in the plant were corrected, and specified sanitary practices, conditions, and procedures were established. (39)

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

Notices of Judgment are prepared by Food, Drug, and Environmental Health Division, Office of the General Counsel, DHEW. Published by direction of the Secretary of Health, Education, and Welfare.

Charles C. Edwards, M.D., Commissioner of Food and Drugs  
Washington, D.C., May 1, 1970

## **FOOD AND DRUG ADMINISTRATION** **~ ORGANIZATION ~**



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## Announcements

**AFDOUS ANNUAL CONFERENCE** The Association of Food and Drug Officials of the United States will hold its 74th Annual Conference June 14-18 at the San Francisco Hilton Hotel, San Francisco. This year's program will include a variety of subjects of importance to the Food and Drug Administration and comparable State and local organizations, to other consumer protection organizations, and to concerned industries.

According to R. Kenneth Buell, chief of the Bureau of Food and Drug, California State Department of Public Health, who is the publicity chairman and president of the Western Association of Food and Drug Officials, the program will be highlighted by the following subjects:

Implementation of the Finch Commission Report of Pesticides  
One Hundred Years of Public Health in California

FDA's Science Activities  
Health Fraud Control

Consumerism  
Food Standards  
Meat Inspection

Report from Canada  
NAS-NRC Drug Efficacy Study  
The States and FDA

Report from FDA Bureau of Foods, Pesticides, and Product Safety  
New Products and Ingredients from the Sea

Report from FDA

Representatives from State and Federal agencies and associate members from the food and drug industries are expected to attend the conference.

**GMP CONFERENCE** The Kansas City District office, FDA, and the University of Missouri, Kansas City, will conduct a Good Manufacturing Practices Conference June 18-19 at Pierson Hall, University Center, 5000 Holmes Street, for food processors, warehousemen, and all others concerned with production of human foods. The conference is designed to bring together leaders in all branches of the food industry and governmental regulatory agencies at Federal and State levels.

Subjects to be discussed will include: U.S. Department of Agriculture regulations, voluntary compliance with regulations, common problems in food laws, and responsibilities of industry.

Acting in support for the conference are the Institute of Food Technologists, Kansas City Section; the Dairy Technologist Society of Kansas City; the American Association of Cereal Chemists, Kansas City Section; and the Association of Operative Millers, District #2.

**OIL MILL INDUSTRY WORKSHOP** FDA will present a one-day workshop to the oil mill industry during the Tri-State Oil Mill Superintendents Association Convention on June 15 at Fort Walton Beach, Florida.

The program will feature experts in various fields of oil mill production, along with FDA personnel from headquarters and from the Atlanta District office. It will include such subjects as storage and care of raw materials, cleaning and sanitation of milling equipment, current good manufacturing practice, identity and life cycle of storage insects, and what the inspector looks for in an oil mill inspection.

**FILM SUCCESS** The FDA-produced film "Good Drug Manufacturing Practices: No Margin for Error" is proving to be a hit. Between August 27, 1968, and January 1, 1970, 86 drug companies have purchased at least one print of the movie, and some have bought as many as five. Purchasers include 26 foreign firms.