

MARCH 1968

FDA PAPERS

ILLINOIS' NEW FDC LAW

A Major Advance
in State Protection

FOOD INDUSTRY GMP's

Why Regulations Are Needed

Drug Efficacy Review

FDA's Plan for Action

HOUSEHOLD HAZARDS

Taking the Wraps off
Harmful Products





"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

Man's increasing use of chemotherapy in the past three decades is exemplified perhaps as well as anything by the discovery of penicillin, the conquest of polio, and the introduction of many other useful drugs. Amid an aura of optimism that man was at last well on the way to conquering most of his ills, it was not surprising that from 1938 to 1962 thousands of new drugs were put on the market. Some of these were the so-called wonder drugs and some, as we have learned, were something less than wonderful.

Although the 1938 statute required that new drugs introduced during this period be safe for use, it is plain that those "safe" drugs which do not do what they are purported to do are really unsafe in that they are relied upon by the ill to effect a result of which they are incapable.

Congress recognized this in 1962 in a climate of mounting public apprehension and enacted legislation to require that drugs be not only safe but also effective. At the same time Congress recognized the possible economic effects on the drug industry and provided a period of accommodation for those drugs introduced between 1938 and 1962.

The waiting period is past. Action must now be taken to carry out Congress' intent that the thousands of drugs put on the market in the past 30 years be both safe and effective. The first step has been taken (see page 7). It is time to get on with the work.

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

Gifford D. Hampshire / Editor

Harold C. Hopkins / Associate Editor

Sheldon Cohen / Art Director

Joan M. Galloway / Managing Editor

Frederick L. Townshend / Production Mgr.

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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.

Advisors to the Editor*

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

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Illinois' new food and drug act

by Douglas C. Hansen

Consumers, taxpayers, and students of efficiency in Government are looking closely at the State of Illinois this year for the possible beginning of a new trend in safeguarding the food and drug supply.

The Illinois General Assembly last year enacted strong food, drug, device, and cosmetic legislation patterned after the Uniform Act which is recommended by the Association of Food and Drug Officials of the United States. Then, State officials asked for and were granted the loan of a topnotch FDA executive to help the State plan and set up machinery to enforce the new law. The loan to Illinois was made under recent Federal legislation providing for interchange of personnel of the Department of Health, Education, and Welfare and of State agencies.

The new Illinois FDC Act, which became effective last January 1, is a unique piece of legislation in one significant respect: It provides that any regulation adopted by the FDA concerning pesticide chemicals, food and color additives, and special dietary foods and food standards automatically becomes the State's own rule unless affirmative action is taken by the Director of Public Health or Agriculture to modify it or reject it, either on his own motion or in proceedings on a petition from an interested party.

The advantage of the automatic adoption provision is that Illinois manufacturers and processors operating in the areas covered will have to comply with only one set of regulations, for a minimum of confusion.

Many of the States which enacted model laws subsequent to the pesticide and food and color additive amendments to the FDC Act may adopt regulations consistent with those of FDA but they first must go through the paperwork and time-consuming procedures of regulation promulgation.

Other features of the new Illinois law that are not found in the Uniform Act nor in most other State laws: A State Inspector must furnish the plant's management a written notice of inspection, must provide a receipt for any samples taken, and must furnish the plant a written list of certain observations made during the inspection. If samples are analyzed, the State must make a report to the plant on the analysis just as FDA is required to do under the Federal FDC Act.

Under the new Illinois law the Director of Public Health also is authorized to promulgate general regulations that conform, insofar as practicable, to general regulations based on the Federal Act.

Dr. Franklin D. Yoder, Director of the Illinois State Department of Public Health, is determined that the State is going to have the best possible protection for its citizens. If he is successful, the State, its cities, and other local government agencies will eventually take over the main burden of assuring the integrity of the food and drug supply.

With two exceptions, food, drug, and cosmetic products produced and sold within a State's boundaries, including that part of a company's output sold within the State while the rest is shipped out of the State,

do not come under the scope of the FDA's interstate commerce mandate. Thus, the protection given to the consumer by State law is all important. The exceptions cover oleomargarine and application of the FDC Act's drug abuse provisions.

All 50 of the States have enacted some kind of food and drug legislation and 34 States have laws modeled after the Uniform Food, Drug, and Cosmetic Act drafted by AFDOUS. The advantages of uniformity are patent and numerous. Some major ones:

- Uniformity in standards and labeling of products. Obviously, a given product can move more freely in commerce if standards and labeling are uniform among the States than if it is offered for sale under a multitude of standards and labeling requirements.

- The body of legal precedent built up in countless actions under the Federal law. Those States with FDC legislation modeled on the Federal law can apply these tested precedents in enforcing their own laws.

- Uniform interpretation from State to State. The knowledge acquired and disseminated by one State can be applied by another.

- Identification by the consumer. The consumer of today is a mobile entity. Uniform standards and labeling help him to identify a product as well in one State as in another, with a minimum of confusion.

Although major enforcement of the Illinois law is the responsibility of the Health Department under Dr. Yoder's direction, certain provisions including coverage of grain, medi-



A partnership between State and Federal agencies in the work of protecting the consumer was contemplated by the Illinois General Assembly when it passed the State's new Food, Drug, and Cosmetic Act. Some of the men who are helping to make the new law meaningful are shown here, from left: Samuel Hart, Director of

FDA's Chicago District; Dr. Roy V. Upham, who heads the new Division of Food and Drugs in the Illinois Department of Public Health; Dr. Franklin D. Yoder, Director of Public Health; and John W. Sanders, Jr., a top FDA executive who is on loan to the State to help set up machinery to enforce the new law.

cated feeds, weights and measures, and some food standards are the responsibility of the Department of Agriculture under Robert M. Schneider. Control of narcotics and certain dangerous drugs often abused remains under Ross V. Randolph, Director of the State Department of Public Safety.

Dr. Yoder recognized the need for high qualifications in personnel selected to administer the new law, and has acquired the services of Dr. Roy V. Upham to head the department's new Division of Food and Drugs.

Dr. Upham brings extensive experience in food surveillance activities from more than 20 years' service in the Armed Forces.

The Department is actively recruiting for other professional people under its merit system.

The Governor of Illinois has appointed a Food, Drug, Cosmetic, and Pesticide Laws Study Commission whose membership of 15 is divided equally among members of the Illinois Senate and the House and representatives from industry. The commission has several func-

tional committees to compile and evaluate all existing State food, drug, cosmetic, and pesticide laws. For example, one committee was appointed to study and recommend legislation on fair packaging and labeling.

Although Illinois began setting up implementation of its new law upon enactment, one important element was lacking: a person with a strong background in all phases of food and drug law enforcement to help plan the new organization and its programs.

Dr. Yoder decided to try to get such an expert through Public Law 89-749, the Federal Comprehensive Health Planning Act of 1966, which authorizes the Secretary of Health, Education, and Welfare to assign experts to work directly with the States for up to 2 years. He appealed to Dr. James L. Goddard, Commissioner of the FDA, for the loan of a top FDA executive to help organize and plan the new unit. This request fitted in with Dr. Goddard's own theories of true partnership between the Federal and local governments, and the man he finally selected to help Illinois is John W.

Sanders, Jr., former Director of FDA's Atlanta District Office. Mr. Sanders is an outstanding executive with nearly 30 years in Government. He is a lawyer and a chemist and has established an excellent record for working with State and local governments to achieve better consumer protection.

Mr. Sanders also was excited over the opportunity to participate in the planning and organizing of what may be a model for consumer protection organizations of the future. He reported for his new duties last November 13 and expects to remain at least 6 months. FDA's John Sanders is the first Government expert detailed to a State under P.L. 89-749, the so-called "Partnership for Health" Act, enacted in 1966.

Mr. Sanders has drafted proposed general regulations to implement the new Illinois Act. Earlier phases of his work have included consultations with State officials in their task of establishing a goal and setting up the new Food and Drug Division to enforce the law in coordination with other divisions of the department and other State, city, county, and

Federal agencies. Besides acting as an advisor to the commission studying existing laws, he is available to Dr. Upham for counseling on a day-to-day basis.

The Federal Government and the State of Illinois apparently are in complete agreement about the direction that should be taken for maximum consumer protection. As Dr. Yoder puts it:

"Rather than approach the problem of consumer protection on the basis of whether a product is shipped interstate or intrastate, we are dealing with the safety of food, drugs, and cosmetics in the broader context of environmental health hazards in much the same way we are attacking the dangers of air and water pollution."

And on his new responsibilities:

"All elements of the 'health team' must work together to eliminate consumer risks. When we speak of the 'health team' we are thinking not only of the Federal, State, and city government officials, but also those in private industry, the academic world, and all professionals with interest in this area."

Encouraging help from other Federal agencies already has been promised for this new step in consumer protection. The U.S. Public Health Service, U.S. Department of Agriculture, and the Chicago District of FDA have offered their support in providing resources and training for the State personnel. Dr. Samuel Andelman, Commissioner of Health of the city of Chicago, has voiced his support for this program.

The Department of Public Health is consulting with other State agen-

cies, the city of Chicago, and other local groups and Federal agencies to plan the consumer protection that will be available for Illinois under the new law.

Dr. Yoder feels there must be a true partnership among all levels of government to eliminate duplication of efforts and to give the taxpayer the most protection for his dollar. This philosophy is consistent with Dr. Goddard's expressed view that eventually most food protection should be provided at the "grass roots" by the States and other local governments. The Federal Government, ideally, would be the coordinator, and also can furnish much of the research and training needed to support these local efforts.

A few skeptics are concerned that such a system may not work because there may be political interference at the local level and lack of financial support. These, of course, could jeopardize any program. If



Douglas C. Hansen is FDA Regional Assistant Commissioner, HEW Region V, Chicago. He joined FDA in 1942.

qualified people must become victims of politics to keep their jobs, the training and changing of employees with the ebb and flow of the political tide would impose prohibitive costs.

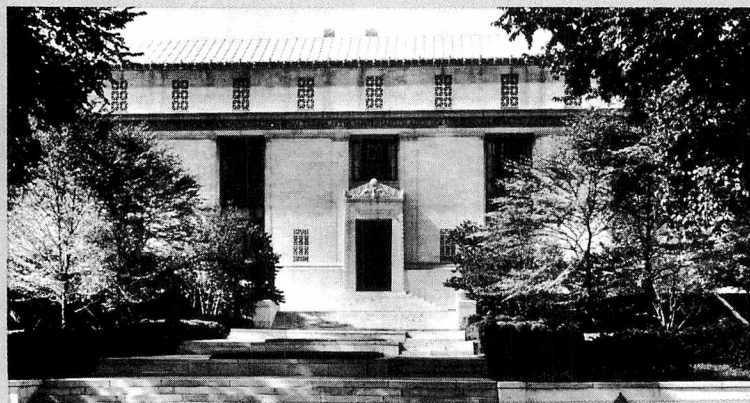
Competent professionals are too much in demand and too short in supply to enter local government service without the protection of an equitable merit system. Illinois is fortunate in having adopted such a system.

A successful program will require funds. The Illinois General Assembly, having enacted the legislation, is now obliged to consider financial support. Dr. Yoder, in addition, has asked for Federal funds under the Comprehensive Health Plan.

The Illinois undertaking is a fresh breeze in the field of consumer protection. It is a forward move by a State government to meet its own problems in food and drug enforcement. It is the type of positive State participation Dr. Harvey Wiley, the first Commissioner of Food and Drugs, had in mind in his statement in 1898 pushing the program for Federal legislation:

"The necessity of National legislation [Federal Food and Drug Law] has long been apparent. For it is evident that State laws, however excellent and well executed, cannot realize their full purpose without the supplement of Federal legislation."

This "pilot" operation in Illinois will be watched closely. It is a practical and efficient approach toward present and future problems. It will help put Federal-State relations in food and drug protection into proper perspective.



The FDA held a Drug Efficacy Review Conference in Washington January 23 to brief the industry and public on the procedures, policy, and timetable the Agency will follow in acting on the findings of the National Academy of Sciences-National Research Council in the latter's study of the effectiveness of those drugs previously approved only for safety between 1938 and 1962.

FDA Commissioner James L. Goddard headed a group of five Agency executives who spoke on the various phases, and Dr. Keith Cannan, representing NAS-NRC, explained the background and purposes of the study and

The Washington briefing on FDA's drug efficacy review

something of the methods and philosophy employed in carrying out the task. Charles Sweeny of the Federal Trade Commission introduced an agreement signed the same day by the heads of FDA and FTC delineating the responsibilities of each in regulating the various areas of drug advertising and labeling.

The talks were succeeded by a question-and-answer period at which several of the speakers acted as a panel to answer questions from industry about the NAS-NRC study and FDA plans. On this and following pages, in slightly condensed form, are carried the entire conference proceedings.

COMPLETING THE TASK

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

I am pleased to welcome you to this meeting, and I trust it will be of help to you, in your professional capacities and in your associations. Our timing is necessarily tied to FDA's plan for action on the drug-efficacy-review reports. Our first such action is a notice published in the *Federal Register* today naming certain drugs for which there is no evidence of efficacy.

Realizing that this first action will receive considerable attention and that it will raise questions as to how FDA will handle other actions, we wanted to take advantage of this opportunity to give you all the information we can at this time.

We do have a plan for action, as you will hear. I want to repeat what I have said on many occasions: we intend to act; we will complete the task Congress gave us in 1962.

It is not a small task, as everyone has recognized. It has even been described as an impossible task—but this view is not permitted to those of us in the Food and Drug Administration. The job cannot be too big or too complex to be done.

The magnitude of the task was made apparent to me shortly after becoming Commissioner.

It was obvious that the Agency did not have sufficient medical manpower to carry out the efficacy review itself. We needed the help of the broader scientific community and a means of bringing to this assignment the Nation's best scientific and medical knowledge. With those needs in mind, it seemed plain enough that one organization was uniquely equipped to carry out the review—the National Academy of Sciences—National Research Council.

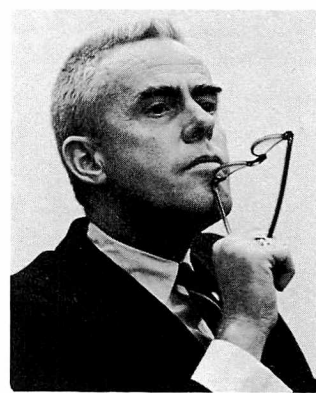
We were indeed grateful when the Academy agreed in May 1966 to undertake this task, and this gratitude is even greater today. Between the time of my original conversation with Dr. Seitz in 1966 and receipt of the first reports from the Academy last fall, the finest scientific and medical minds in America have given many months of dedicated and objective study to this important project.

We are honored today to have with us Dr. Keith Cannan, former Chairman of the National Research Council's Division of Medical Sciences. It was under Dr. Cannan's leadership that this organization undertook the study.

We are indebted to the advisory committee set up under the chairmanship of Dr. William S. Middleton, Dean Emeritus of the University of Wisconsin School of Medicine, and chairman of the NRC Drug Research

Board. This committee selected the members of the review panels, developed the guidelines to be followed by the panels in making their judgments, and coordinated the recommendations from the panels for submission to FDA.

The guidelines were drafted by an ad hoc group under the guidance of Dr. Alfred Gilman, Professor and Chairman of the Department of Pharmacology at the Albert Einstein College of Medicine. The draft guidelines were offered for discussion at an Academy conference in July 1966. At that time, representatives of the



We are used
to change.
Change is
the norm

drug industry, the professional and scientific community, and other interested parties were invited to comment.

Another ad hoc committee developed the categories of drug usage in which the drugs were grouped for review. This work was guided by Dr. Walter Riker, Professor and Chairman of the Department of Pharmacology, Cornell University Medical Center.

By agreement, members of the panels shall remain anonymous, save to their colleagues, but we must still gratefully acknowledge the contribution they have made to the improvement of drug therapy.

Throughout this review Duke Trexler, Executive Secretary of the Drug Research Board, has been a guiding force.

The FDA, the drug industry, physicians, pharmacists, and interested citizens have been going about their affairs these past 20 months with an awareness that the NAS-NRC drug efficacy review was underway. There have been varying degrees of awareness, of course. In my own talks before various groups around the country, I have frequently alluded to the study and its implications for the future. The purpose, of course, was to prepare everyone concerned for the action phase which follows submission of the panel reports.

That is our primary reason for calling this meeting. We have worked out an orderly procedure for taking action on the panel reports, and we wish to share that information with you. While we are determined to take the necessary and appropriate action on the reports, we are quite aware that our action calls for a reaction by the affected and interested parties. It is our intention to

act in an orderly manner so that the reaction can be equally orderly.

I hope this will be the case. It will be if we keep in mind our fundamental objective—better patient care. That objective has been the guiding principle for the experts who have been making the scientific and medical judgments in the study. In the final, difficult moments of judgment they have asked and answered the question: “What is the best of all possible decisions in the interest of patient care?”

The FDA intends to carry on in the same spirit of objectivity. In doing so we will be aware of the business judgments to be made. We will strive to make it possible for those business judgments to be based upon a clear understanding of the scientific and medical judgments before us.

This is not a new idea for any of us. We are constantly revising our thinking in light of new scientific evidence. We are used to change. Change is the norm; status quo is the exception. So changes in our thinking about these drugs will not surprise anyone.

I am confident that we can cooperate to complete this task successfully. Let us decide to do that.

NAS-NRC BACKGROUND

by R. Keith Cannan, National Academy of Sciences/National Research Council

Thank you, Commissioner Goddard, for your generous remarks.

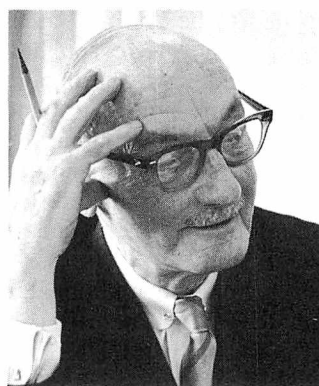
When we first engaged ourselves with this undertaking I anticipated that we would encounter some troubled waters. But I feel considerably relaxed this morning, and this is due in large measure, Mr. Commissioner, to the splendid cooperation and support that we have received from the FDA and to the generous cooperation and restraint of the profession and of industry. I am inclined to extend the same tribute to the press, although it may be that we have not been harassed by the press because we are less newsworthy than we had thought we would be.

I think you are all familiar with the origin and purposes of the Academy study; otherwise, you would not be here today. But, by way of background, it was in July 1966 that the Academy signed a contract with FDA to undertake an evaluation of all drugs for which New Drug Applications had been approved between 1938 and 1962, that is to say, all of these drugs that the industry wished to retain on the market. In July also, the industry was invited by FDA to submit presentations and supporting data for all therapeutic claims for drugs that it wished to have evaluated by the Academy.

That was in July. By the end of September, the Academy had organized itself, assembled a staff, developed the guidelines for the study, appointed a policy committee, and 27 panels of experts. By the end of September, also, the bulk of the industry's presentations was already in the hands of FDA. So it was that 15 months ago we really got under way.

How is the task shaping up? A total of 237 pharmaceutical firms submitted presentations on some 3,600 drug formulations. The majority of these drugs had claims for effectiveness in a variety of specified clinical conditions. Each individual claim, either explicitly formulated or implicit in the wording of the package inserts, has been or will be separately evaluated. In the course of doing this, many drugs have been reviewed by a number of panels. A few drugs, indeed, have been assigned to as many as 10 or 15 panels.

Overall, I would guess that something like 10,000



*Overall, I
would guess
something
like 10,000
judgments*

independent therapeutic judgments will have been made when the task is completed.

Where are we today? In an audit that we made just a week ago, we estimated that 89 percent of these individual therapeutic judgments have now already been made. Something like 47 percent of the reports from panels on individual drugs have been edited and bibliographies checked. What remains to be done is mainly the consolidation of the inputs of the several panels into coherent reports on individual drugs.

We still hope that the great bulk of this work will be completed by June 30 this year, but there certainly will be some spillover beyond that time.

Just a word on what the reports look like. For each therapeutic indication a categorical classification has been made of degree of effectiveness. The categories are: “effective”; “probably effective”; “possibly effective”; “ineffective.” In addition to these, the panels have found it necessary in many situations to use a fifth category: “Effective, or probably effective, but—.”

Where effectiveness has been qualified, the reports will contain a justification for the qualification. Some of these justifications are quite extensive and run into several pages.

In many cases the panels are recommending modifi-

cation in the wording of labeling and inserts, to conform to the judgments that the panels have made, and, often, the reports will be accompanied by general comments on classes of drugs and classes of therapeutic effect.

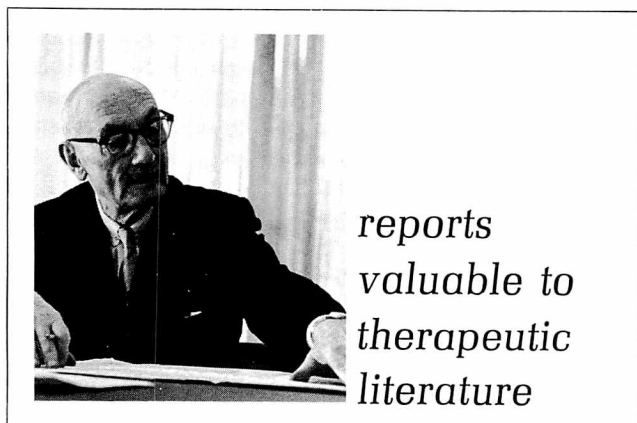
Now, I have heard it said that the recommendations of the Academy will be that such-and-such a drug shall be removed from the market. However, I would remind you that it is the individual claims that have been evaluated and not the drug as an entity. It will be only in that unusual situation in which all claims have been rejected that the Academy's report can be interpreted as a recommendation that the drug should be removed from the market.

We feel that these extended reports will be a valuable contribution to the therapeutic literature, and we hope—and the FDA hopes also—that they will, in due course, be widely disseminated.

Some 3 months ago, at the request of FDA, we submitted 21 reports that happened to be "on ice" at that time, and ready for transmittal. They were sought by the FDA so that the Agency might have the opportunity to begin to design appropriate machinery to handle the great mass of material that would be coming to it. This small batch of reports is not a random sample of the whole. One should not attempt to extrapolate from this sample any generalizations on the tenor and impact of the results of the overall study.

Today we have well over a hundred additional reports ready for transmission to FDA. Thereafter, we hope, in rapid succession, to formally transmit other batches of a hundred or more to FDA.

When will these reports be released to the public? The panels have worked under a cloak of confidence throughout the study, and as I have indicated, that confidence has been respected. The panels have not been subject to external harassment or distraction. The integ-



rity of the study has been preserved.

The reports will be submitted in confidence to the FDA. The Academy will not itself release any information on their substance. It has been agreed, however, with FDA that the reports will be released to interested parties verbatim and intact.

The timing of the releases must be left to FDA, but I think I can assure you that the FDA is just as anxious to get these materials into the public domain as we in the Academy are to have them released.

Meanwhile, the officers of the Academy and all their committeemen and panel members have been urged to refrain from responding to all inquiries respecting the reports and to refer them to the FDA. This may seem to be a posture of Olympian detachment, but I think you will agree that any other course would result in a babble of voices that would lead only to confusion.

ADMINISTRATIVE MEDICINE

by Herbert L. Ley, Jr., M.D.

Director, Bureau of Medicine, FDA

Dr. Goddard has called this a task to be completed. The Bureau of Medicine now has the responsibility within FDA of reviewing the reports received from the National Academy of Sciences-National Research Council, recommending the action to be taken and reviewing the submitted data, including original and supplemental New Drug Applications.

To accomplish this task, we have formed a Task Force headed by Dr. Paul A. Bryan, Deputy Director of our Office of Marketed Drugs. This Task Force will have available the resources of the entire Bureau of Medicine and will utilize those specialists in each of the Offices and members of our Advisory Boards to complete this task within the 3 years we have allotted this problem. Of course, the review and processing of the NDA's and other submissions for many drug products will be completed prior to that time.

You may have already seen the announcement on bioflavonoids which was published in the *Federal Register* today.

The reports which we receive from the National Academy of Sciences-National Research Council Drug Efficacy Study will be routed from the Director for NAS-NRC Liaison, Dr. Ralph Smith, to the Task Force for the implementation of the necessary review. Based on the Academy's recommendation and their review, the report will be assigned to one of the four following categories:

1. Those drugs generally recognized as safe and effective for the labeled indications and marketed for a material period of time and to a material extent would be considered to be not new drugs. The labeling conditions under which the drugs will be classified as "not new," and any other conditions essential to this determination will be published.

A Task Force decision to classify a drug as a "not new drug" is not to be construed by the manufacturer as a statement that the new-drug status of the article

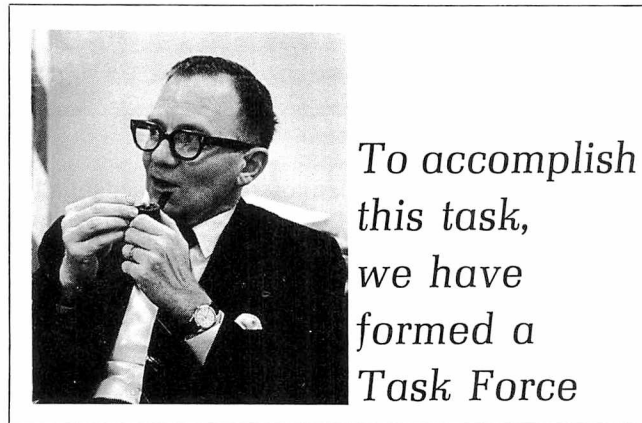
is determined once and for all. FDA reserves the right to require a manufacturer at any time to furnish the Agency with full information about such a drug that would have a bearing on its new-drug status.

2. Abbreviated supplemental or abbreviated original NDA's will be required for certain drugs for which any or all of the following criteria apply:

- a. A lack of scientific evidence or of NAS endorsement of efficacy for the indications presented;
- b. Concern regarding toxicity or possible serious side effects;
- c. Evidence of lack of or reasonable doubt of biologic equivalency of various brands of the same drugs;
- d. Use of the drug in treatment, management, or prevention of serious illness in which lack of biologic equivalency would pose a hazard to health.

This group may include the reports listed "effective," "effective but," some of the "probably effective" and some of the "possibly effective" reports. The abbreviated NDA's will consist of:

- a. Labeling and formula submissions;
- b. Statement concerning compliance with GMP and any special controls that may be needed;
- c. Statement on conformance with USP or NF specifications, or, when needed, additional specifications in the NDA file;



- d. Statement regarding where the drug is manufactured;
- e. Blood level studies or other appropriate tests, where required.

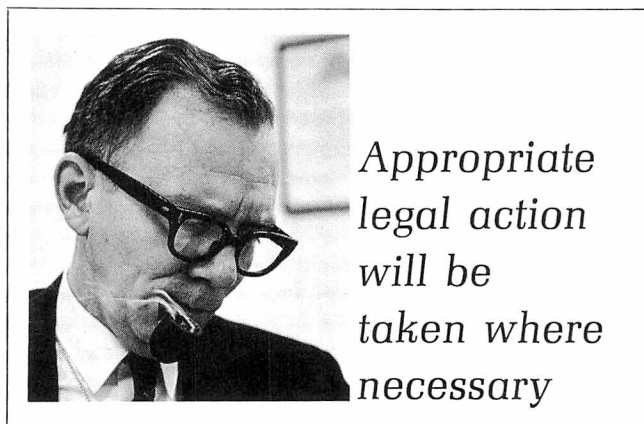
The requirements for an abbreviated NDA will be determined following review of the Drug Efficacy Study recommendation by the Task Force.

3. Those drugs for which clinical studies or other evidence is needed to prove effectiveness will require the submission of more complete NDA information. Drugs in this category will include the majority of those drug reports listed as "possibly effective."

4. Approval of New Drug Applications will be withdrawn for those drugs regarded as "ineffective."

When necessary, full disclosure labeling and additional specifications to be required will be developed from the preliminary review. Each manufacturer holding an NDA will be provided with a copy of the Academy recommendation regarding his product.

Following this initial review and judgment by the Task Force, a meeting will be requested with representatives of the manufacturers holding a New Drug Application for the products involved in the study and any other manufacturers who may be affected. At this



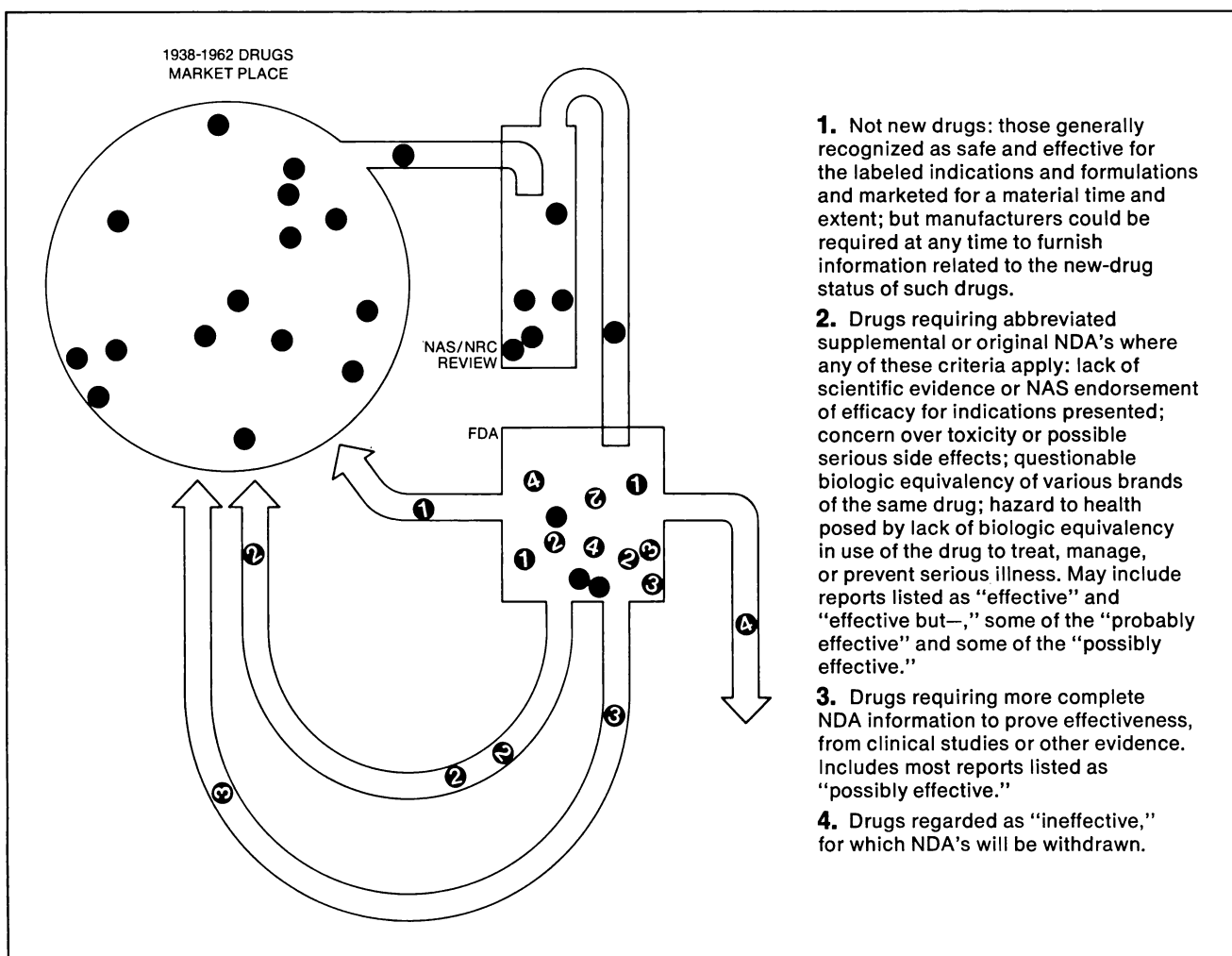
meeting the Academy's report on the NDA's being considered will be distributed to all interested parties together with our recommendations regarding the drug.

An appropriate *Federal Register* statement containing our recommendations regarding the drug and our intent will be prepared and published.

On the basis of the *Federal Register* statement and discussion with interested manufacturers, additional submissions regarding the drug being considered will be received. Those submissions of a complete NDA will be handled according to the new-drug procedure in the Office of New Drugs, Bureau of Medicine. Regular submission of supplemental NDA's will be handled by the Office of Marketed Drugs. Those submissions of labeling formulation of drugs regarded as not new drugs will be reviewed for compliance with the *Federal Register* statement by the Task Force. Those submissions of an abbreviated NDA will be reviewed by the Task Force and appropriate action, either approval or non-approval, taken.

If the abbreviated NDA is not approved, an original NDA must be submitted to the Office of New Drugs. FDA handling of all of the submissions will be coordinated by the Task Force. We will not attempt to send letters to those manufacturers who have not expressed their intention to comply. Our Field District Offices will be requested to visit those firms which do not reply to the *Federal Register* announcements to obtain material for review to determine the degree of compliance or noncompliance.

District Offices will also be inspecting other affected firms to determine their degree of compliance with this



program as well as the other requirements of the Act.

While we hope to achieve maximum voluntary compliance, appropriate legal action will be taken where necessary to insure that compliance is achieved.

LEGISLATIVE BACKGROUND

*by William W. Goodrich
Assistant General Counsel
Food and Drug Division, HEW*

The most basic provisions of the Kefauver-Harris Drug Amendments of 1962 were those which require that all drugs be proved effective as well as safe for their intended uses.

Secretary Ribicoff, testifying in September 1961 on Senator Kefauver's bill, called attention to a number of drugs that had been cleared through the "new drug"

procedures on consideration of safety alone and that were being promoted to the medical profession without adequate support of clinical data. He called this indefensible.

First on his list of such drugs, interestingly enough, were citrus bioflavonoid compounds which are the subject of the first efficacy review to be reported to FDA by the NAS-NRC Drug Efficacy Review groups. The NAS, like the Secretary in 1961, classifies these drugs as ineffective for any purpose. And now, more than 6 years after the Department's views were laid on the record, the Agency has started the process to remove them from the market.

How the Agency was to deal with the problem of reclearance of claims of effectiveness for all of the previously approved new drugs, those marketed between 1938 and 1962, became one of the central points of controversy before the Kefauver bill was enacted into law.

The bill as first reported by the Senate Judiciary Committee on July 19, 1962, left the definition of what was a new drug unchanged. An article was a "new drug" if it was not generally recognized by qualified

experts as *safe* for its intended use. This definition did not include efficacy. And it would not have required efficacy review for any drug unless its safety was in question.

Sections 505(d) and (e), 21 U.S.C. 355(d) and (e), were amended, however, to authorize the Secretary to withhold approval and to withdraw approval of applications for new drugs (those not generally recognized as safe) if there was a lack of substantial evidence that the drug would have the effect it purported or was represented to have or if the labeling of the drug was false or misleading in any particular.

The practical effect of this, as explained in the Committee's Report, S. Rept. 1744, Part 1, page 17, was to make it unnecessary that "many 'old' established drugs might have to go through the burdensome new drug clearance procedure even though their safety was unquestioned." The Committee said that the FDA should exercise its power to proceed by seizure against any safe drugs for which unsupported claims of effectiveness were being made.

On August 3, 1962, President Kennedy wrote to Senator Eastland enclosing drafts of amendments to the reported bill which he regarded as essential to consumer protection. The purpose, the President explained, was "to help assure the American people that *any drug on the market today* is safe and effective for its intended use." [Emphasis added.]

Amendment 4 offered by the President was entitled



most basic
provisions of
the Kefauver-
Harris
Amendments

"Effectiveness and Safety of New Drugs." The explanation of the amendment was as follows (108 Cong. Rec. 15696, August 6, 1962):

Definition of "New Drug." Section 8 of S. 1552 does not add to the definition of the term "new drug" in existing law the concept of "effectiveness." This is necessary in order to assure that all new drugs will have to be proved effective as well as safe for the uses for which they are offered as is provided in the Harris bill (H.R. 11581).

The Harris bill also contains appropriate transitional provisions which would require a commercially established drug to go through the "new drug" process only

(a) where we find that there is substantial doubt as to its efficacy, (b) where the new drug clearance has been withdrawn on other grounds, or (c) where an amended New Drug Application is submitted.

With these provisions, it would make clear that the amendment to the definition of "new drug" would not



to assure
that any
drug... is
safe and
effective

require the resubmission of all the thousands of "new drugs" hitherto cleared for the market in order to obtain reclearance for efficacy.

Standard of Proof of Effectiveness. Section 8 of S. 1552 requires "substantial evidence" of effectiveness to be submitted with each New Drug Application. This standard of proof is inadequate in terms of assuring that drugs that reach the market have been shown to be effective for the claims made for them.

Additional Grounds for Suspension or Withdrawal of Approved New-Drug Applications. Section 8(c) of S. 1552 authorizes the Secretary, after notice and opportunity for hearing, to suspend the effectiveness of a New Drug Application when new evidence raises a "substantial doubt" as to the safety of the product.

... In addition, the Harris bill extends this authority to suspend when

(c) A substantial doubt of efficacy exists.

The Senate Committee accepted the recommendation, amending the definition of "new drug" to introduce the "not generally recognized as effective" concept, and coupled this with transitional provisions (a "grandfather" clause) to deal with previously cleared drugs which were not generally recognized as effective for their intended uses.

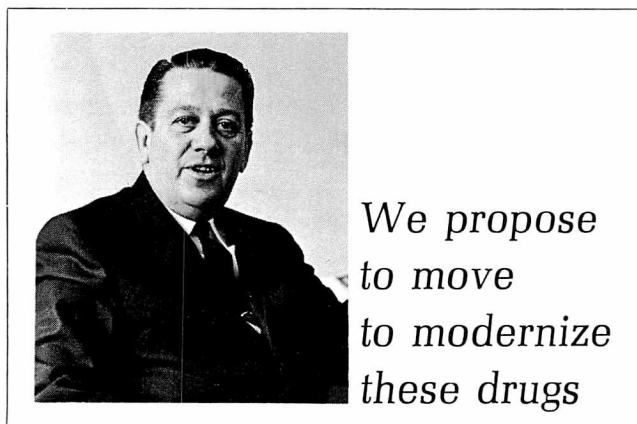
Under the bill as reported on August 21, 1962, S. Rept. 1744, Part 2, pp. 5-8, the Committee explained that the new definition of "new drug" would "require that all claims for effectiveness, whether made initially in a new drug application or at any time thereafter, must be supported by 'substantial evidence' which term is defined in the substitute amendment."

The effect of this amendment on drugs already on the market was explained under the discussion of the transitional provisions. On this, the Committee said:

... Under the amendment, a drug which is on the

market and has gone through the new-drug procedure would not have to be resubmitted for clearance of existing label claims with respect to effectiveness of the drug unless approval of the new drug is withdrawn or suspended under the act or unless an amendment or supplement to the effective New Drug Application is filed (in which event only the changed labeling would be reevaluated).

Secondly, under this transitional provision the new grounds for withdrawing approval of a new drug already on the market under the new authority relating to drug effectiveness would not apply until 2 years after the bill is enacted unless approval of the new drug is withdrawn



or suspended earlier on other grounds.

Thirdly, in the case of a drug on the market which was never subject to the new-drug procedure before, the amendments to the new-drug definition relating to drug effectiveness would not apply to existing labeling claims.

This same explanation appears in the House Committee Report, H. R. Rept. 2464, p. 12, and in the Conference Committee Report, H. R. Rept. 2526, pp. 22-23.

This plainly shows that any drug that had ever been subject to the new-drug-clearance procedures would be subject to reevaluation and withdrawal on its claims of effectiveness. A 2-year delay was provided for the holders of New Drug Applications to assemble any needed evidence to support the claims they were making, and the Department was authorized beginning October 10, 1964, to initiate proceedings for the withdrawal of approval of any previously approved new drug on the grounds that there was a lack of substantial evidence to support the claims.

Since the congressional purpose is so clearly expressed, the question arises whether the legislative language actually adopted failed to accomplish the purpose and left undisturbed the drug manufacturers' rights to continue in perpetuity the promotion of some drugs generally recognized as safe on October 10, 1962, with unsupported claims of effectiveness.

We think the "grandfather" clause did not do this.

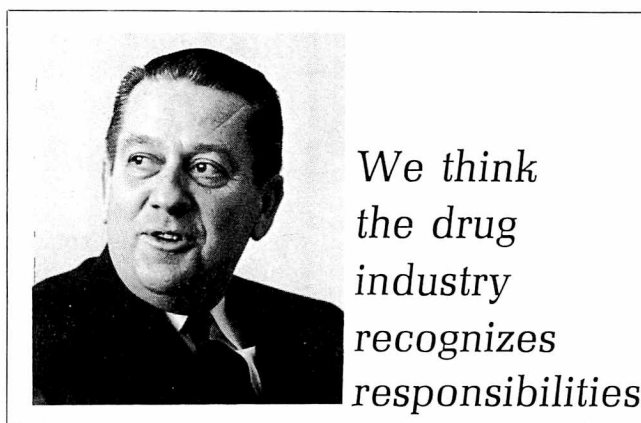
Subparagraph (c)(3) of the transitional provisions, Section 107 of Public Law 87-781, dealt with all drugs

that had been cleared through the new-drug procedures. It provided that these drugs did not have to be recleared by the fresh submission of New Drug Applications so long as no changes in the claims were made. Any changed use or condition of use did have to be cleared. This appears in subparagraph (c)(3)(A). The next subparagraph, (c)(3)(B), authorized the Department after a lag period of 2 years to initiate withdrawal proceedings against any such drug, even though the claims were not changed, on the grounds that there was a lack of substantial evidence of efficacy.

The last part of the "grandfather" clause, subparagraph (4), applied to drugs on the market on October 9, 1962, which were not on that date "new drugs" (drugs which were generally recognized as safe for their intended uses), and which were not covered by an effective application. Those drugs were given permanent protection from the new-drug-efficacy requirements, so long as no changes were made either in the drug or in its labeling. All of the legislative history explains that this was limited to drugs which had "never previously" been subject to new-drug clearance.

Consistent with this legislative mandate we have sought and obtained a scientific reappraisal of every drug now on the market that was once cleared through the new-drug procedures. We propose to move with this scientific support, on a drug class basis to modernize these drugs, both as to composition and claims, to assure effectiveness in clinical use and in self-medication. Those that are ineffective will be removed from the market. Those that are effective, but require labeling or compositional changes, will be brought into compliance. Those that are possibly effective or probably effective will be given a reasonable delay for assembling medical evidence, and then brought into compliance.

We have available to accomplish the high purpose of making "every drug on the market today" safe and



effective for its intended uses a variety of administrative and judicial sanctions.

We hope none will be required. Instead, we think the drug industry—large and small—recognizes that marketing drugs carries responsibilities to the patient and his physician as well as to the law.

This demands that all claims for effectiveness conform to the substantial medical evidence. Consultants drawn from the best of the Nation's experts are completing their reviews and offering their judgments as to the validity of current promotional claims.

We hope the industry will join us in translating those judgments into promotional messages as promptly as possible.

PUBLIC NOTICE ON NDA WITHDRAWALS

by Julius Hauser, Assistant for
Regulations, Office of the Associate
Commissioner for Compliance, FDA

This discussion is concerned with the procedures that will be employed by FDA to furnish public notice and information concerning the proposed withdrawal of new-drug approvals. There have been few such actions in the past. Interest in these proceedings is heightened in anticipation of actions on the reports of the National Academy of Sciences-National Research Council review of claims of effectiveness for drugs "deemed approved" between 1938 and October 10, 1962.

It is not now the intent of FDA to promulgate regulations establishing a new set of fixed procedures for withdrawing approval of New Drug Applications or for furnishing public notice and information concerning such action. We believe that existing provisions of law and regulations furnish generally sufficient authority to FDA, protection of the rights of applicants and the public, and satisfactory procedures with respect to actions withdrawing approvals of NDA's, revocation of orders withdrawing NDA approvals, notice of proposed actions, and information concerning them.

Specifically, sections 505(e), (f), (g), and (h) of the FDC Act and most of sections 130.14 through 130.34 of the regulations present the rules concerning such actions. Section 130.14 of the New Drug Regulations provides that notice of opportunity of a hearing on a proposal to withdraw approval of a New Drug Application will be published in the *Federal Register* and that such hearings will be open to the public except for portions containing information concerning a method or process entitled to protection as a trade secret. Section 130.34 of the regulations provides that notice of withdrawal of approval of an application will be published in the *Federal Register*.

Other provisions of law and regulations relating to the disclosure of information are contained in the Public Information Act (Public Law 90-23) and the Department of Health, Education, and Welfare's regulations thereunder (45 CFR Part 5), section 301(j) of the Federal Food, Drug, and Cosmetic Act, FDA's regula-

tion on disclosure of official records and information (21 CFR Part 4), and section 130.32 of the New Drug Regulations.

These existing provisions of law and regulations furnish an adequately defined yet flexible framework for proceedings to implement the conclusions reached on the basis of the NAS-NRC review of drug effectiveness. For example, when FDA concludes that an article is ineffective for any drug purpose, a variety of procedures may be employed within this framework with a view to the withdrawal of all NDA approvals and removal of the drug from the market. One approach is illustrated by the recent action withdrawing approval of all NDA's for drugs for human use containing bithionol. Although this action was based on a question of drug safety, the same procedure may be employed on a question of drug effectiveness.

In the bithionol case, FDA corresponded directly with each of the eight applicants who had new-drug approvals for bithionol preparations, informed them of the proposed action and invited a written waiver of an opportunity for a hearing unless the firm wanted a hearing. Only one of the eight firms did not submit such a waiver. Following this correspondence, FDA published in the *Federal Register* of July 19, 1967, notice of opportunity for hearing to this one applicant and any other interested person who would be adversely affected by an order withdrawing approval of the named applicant's product and all other drugs for human use containing bithionol.

The *Federal Register* statement included a concise



Existing
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authority

presentation of the question of safety underlying the proposed action. It gave notice that promulgation of the proposed order will cause all drugs for human use containing any bithionol to be new drugs for which no approval is in effect. Subsequently, when no one wanted a hearing, FDA published in the *Federal Register* of October 31, 1967, an order withdrawing approval of all of the subject NDA's, naming them, setting out the grounds for the action and stating that "upon promulgation of this order, all drugs for human use containing any bithionol will be regarded as new drugs for which no approval is in effect." It should be noted that this action established a basis for removing from the market

on a new-drug charge not only the drugs which were specifically the subject of prior new-drug approvals, but also any "me too" drugs. With industry cooperation it was accomplished without litigation but furnished through *Federal Register* publication full information and opportunity for any interested person to contest the action.

An alternate approach, differing only in detail from the bithionol action, is illustrated by the proposed action on drugs for human use containing rutin, quercetin, hesperidin, or bioflavonoids, which should be the subject of a *Federal Register* statement today. This statement may be summarized, as follows:

It furnishes the information that FDA has concluded that there is no evidence that rutin, quercetin, hesperidin, or bioflavonoids are effective for use in man for any condition. It discloses that the Commissioner intends to publish a notice of opportunity for a hearing on a proposal to withdraw approval of all NDA's for drugs containing these substances. It gives notice that such an order will classify all drugs containing any of these components as new drugs for which an approval is not in effect. It invites the holders of new-drug approvals and any other person who may be adversely affected by the proposed action to a meeting with FDA to discuss the procedures and to identify and resolve any problems. Presumably, this *Federal Register* statement will be followed by publication in the *Register* of notice of opportunity for a hearing and in due course an order withdrawing approval of all such NDA's.



*desirable to
seek the
fullest
cooperation*

FDA is not limited within the framework of the existing provisions of law and regulations to the procedures followed in the bithionol and rutin situations. The rules permit the Commissioner to publish in the *Federal Register* notice of opportunity for a hearing on a proposal to withdraw new-drug approvals when there is a question of drug safety or effectiveness without advance correspondence or preliminary meetings.

However, we believe it is desirable not only to seek the fullest cooperation of the drug industry in removing ineffective drugs from the market and unsubstantiated claims from drug labeling, but also for this Administration to show a reasonable consideration for the prob-

lems of industry in connection with these actions. This, of course, does not mean that we are committed to any undue delay in actions necessary to assure the safety and effectiveness of drugs.

The procedures to require removal of unsupported claims from the labeling of useful drugs "deemed approved" under the new-drug provisions are similar although more involved than those described for removing worthless drugs from the market. In general, FDA will try to accomplish these objectives without interfering with the continuing availability of useful drugs. However, the cooperation of drug manufacturers



*industry
suggestions
concerning
procedures*

may be necessary to avoid a temporary discontinuance of drug marketing. Withdrawal of NDA approvals is needed to establish a strong basis for requiring needed labeling changes in "me too" drugs as well as those specifically covered by NDA approval.

Under transitional provisions of the Act a drug "deemed approved" prior to October 10, 1962, becomes subject to the amended definition of "new drug" that includes the concept of effectiveness only when the NDA approval is withdrawn. For these reasons, FDA may withdraw approval of a useful drug that includes unsupported claims in its labeling and simultaneously approve a supplemental application with labeling including only those claims for which the drug is effective. Continuity of marketing need not be broken.

This procedure would facilitate regulatory proceedings against any brand of the same drug, in the generic sense, on a charge that the article is a new drug for which an application is not approved.

An example of this kind of procedure is illustrated more or less by recent actions involving potassium salt preparations intended for oral ingestion by man. These actions are covered by a notice of opportunity for hearing published in the *Federal Register* of May 8, 1965, proposing to withdraw approval of New Drug Applications for potassium chloride tablets, the order withdrawing approval of these applications published in the *Federal Register* of September 17, 1965, and the related statement of policy published as section 3.15 of the regulations in the *Federal Register* of April 24, 1965.

As in the case of the actions involving withdrawal of

new-drug approvals for worthless drugs, the actions limiting the claims for useful drugs may be developed with variations in detail within the established framework of law and regulations. In all cases, publication in the *Federal Register* will be utilized to inform interested persons of the action proposed, the basis for it and the implications of the proposed order with regard to the continued marketing of a drug, the need to submit supplemental NDA's, and any requirement for the submission of original NDA's. When original New Drug Applications are required, the *Federal Register* statement may indicate those parts of an NDA that may ordinarily be considered sufficient for an approval, taking into account the fact that the drug may not be altogether novel.

The *Federal Register* publications will, of course, furnish full opportunity for the applicant and any person who may be adversely affected by the proposed order to have a hearing and judicial review as required by law. The *Federal Register* statements may provide for informal conferences for discussion of the procedures and implications of the proposed action. *Federal Register* statements may elaborate the drug labeling required for approval of a supplemental NDA, an original NDA, or that will permit continued marketing of a drug without a new-drug approval.

In conclusion, we find that existing provisions of law and regulations provide a clear yet flexible framework within which FDA can employ reasonable procedures to accomplish the purposes of the NAS-NRC review of drug effectiveness. FDA will welcome constructive industry cooperation in this program. We will also welcome industry suggestions concerning procedures that will expedite the accomplishment of the objectives to assure the effectiveness of marketed drugs.

PRESCRIPTION DRUG ADVERTISING AND PROMOTIONAL LABELING

*by Dr. Robert S. McCleery
Bureau of Medicine, FDA*

NAS-NRC efficacy study panels have labored arduously and assiduously in the public interest. They have studied the available data on each of this great group of potentially therapeutic agents, and they have proposed parameters for safe and effective use. Their considerations may lead, among other actions, to a revision, or creation, of package labeling for each drug.

It would be difficult to overemphasize the importance of the potential that the panels' work provides for improvement of the quality of care that can be offered by



*a revision,
or creation,
of package
labeling*

the medical profession. As significant as the approaching revisions are, in themselves, they will achieve their full impact of increasing the precision with which physicians use these drugs primarily through the manufacturers' promotional activities by their detail men, journal advertisements, direct mail, etc.

Changes that occur in labeling of prescription drugs as a result of NAS-NRC reviews, and of the subsequent actions by the FDA, will be taken into account in our future monitoring activities. From the standpoint of the Division of Medical Advertising, the adjusted package labelings will have the same status as authorized labelings that have been submitted as supplements to New Drug Applications, for example.

Under the regulations, a reasonable time is permitted to elapse before promotional labeling and journal advertising must reflect package labeling changes. The regulations do require prompt revisions, however. Ordinarily, we assume that promotional labeling and advertisement can be made consistent with revised package labeling within 90 days from the date that labeling is approved or placed into effect under the provisions of Regulation 130.9 (d). We expect to continue to use the 90-day period as a working guide in our surveillance



*We will
sample the
promotional
activities*

programming for these drugs.

As a final point, we do not wish to mislead anyone into believing that FDA surveillance over prescription

drug promotion is 100 percent, or that it will be 100 percent in relation to drugs that have come under the NAS-NRC review program. However, we can assure you that we will sample the promotional activities on this group of prescription drugs, and that we will apply the same concepts in our judgment as you have come to expect on promotion of other prescription drugs.

LIAISON AGREEMENT

Remarks of Charles A. Sweeny, Director Bureau of Deceptive Practices, FTC

I consider it entirely appropriate that the Federal Trade Commission be represented at this meeting and am highly honored to be its representative.

I am sure you are all familiar with the fact that in appearances before congressional committees, and on other occasions, Chairman Paul Rand Dixon has from time to time referred to earnest discussions he has been having with Dr. Goddard pursuant to their mutually shared determination that the activities of the two Agencies be coordinated to the fullest extent possible in the public interest.

I am sure, too, that most of you are familiar with the announcement last July 6 that the Commission was initiating a Trade Regulation Rule proceeding regarding the advertising of nonprescription systemic analgesic drugs. One of the proposals was that it would be a violation of the FTC Act to disseminate any advertisement for such a product which:

"Contains any representation with respect to efficacy or safety which contradicts, or in any manner exceeds,



FTC and
FDA have
formalized
an
understanding

the warnings, statements, or directions for use appearing on the label or in the labeling of such product."

It is my privilege to contribute to your program today the information that as the latest development in this trend the FTC and the FDA have formalized, in writing, an understanding with respect to liaison and working relationships.

The agreement as approved and signed

It is recalled that the Secretary of the Department of Health, Education, and Welfare and the Chairman of the Federal Trade Commission entered into an agreement in June 1954, "for the purpose of avoiding duplication of work and to promote uniformity and consistency of action in areas where both agencies have a concern and the actions of one agency may affect proceedings by the other."

The practical effect of that agreement was to assign primary responsibility for preventing misbranding of foods, drugs, devices, and cosmetics to the Food and Drug Administration; primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of such products being assigned to the FTC.

Developments, including changes in statutory authority and the nature of regulatory problems encountered since that date demonstrate an urgent need for updating that agreement.

It is becoming increasingly clear that we must assure, in this vital field of public health, that the statutory authorities and procedures, and the manpower and other resources, available to each Agency are so employed as to afford maximum protection to the consumer. This means joint planning of coordinated programs, exchange of information and evidence to the extent permitted by law, by the staffs of both Agencies in appropriate undertakings, and the careful selection of the procedure of either Agency (or simultaneously by both) promising greatest benefit to the public.

In approaching the subject of liaison as it relates to the advertising of over-the-counter drugs, we are cognizant that from a regulatory viewpoint such drugs fall into several categories as follows:

(a) Post-1962 drugs which the FDA has reviewed under the NDA procedure and for which a determination with respect to both safety and efficacy has been made.

(b) Post-1938 but pre-1962 drugs which the FDA has reviewed under the NDA procedure for safety but not efficacy.

(c) Pre-1938 drugs and those post-1938 drugs not heretofore subject to the NDA procedure and which the FDA has not otherwise formally evaluated as to safety or efficacy.

(d) Drugs whose safety or efficacy or both has been determined by the FTC, or by the FDA in an enforce-

by James L. Goddard, M.D.,
Commissioner, FDA, and
Paul Rand Dixon, Chairman, FTC

ment proceeding. This category would include, for example, efficacy determinations resulting from Federal court litigation under the Federal Food, Drug, and Cosmetic Act, and proceedings brought under the Federal Trade Commission Act. Some of these will be reviewed under the NDA procedure.

(e) Drugs involved in the current NAS-NRC efficacy review.

With respect to the advertising of drugs the following guiding principles will govern interagency liaison:

A. For pre-1938 and those post-1938 nonprescription drugs which the Administration has not evaluated as to safety and efficacy, liaison fully employing the scientific and legal staffs of both Agencies will determine how best to proceed against any practices raising questions of law violations subject to the jurisdiction of both Agencies. Particular consideration will be accorded determinations resulting from legal proceedings by either Agency, bearing in mind the relative degrees of proof necessary to support, and the differing remedies provided by, seizure actions, injunctions, and prosecutions under the Federal Food, Drug, and Cosmetic Act, and Federal Trade Commission cease and desist orders, and the possible applicability of the doctrine of res judicata.

B. For products subject to NDA or certification procedures, the Commission will ordinarily accept the Administration's determinations and will attempt corrective action under the FTC Act with respect to claims in advertising which are inconsistent with such determinations. For those drugs covered by the NAS-NRC efficacy review, FDA will make the panel reports available to FTC, together with FDA's actions on the reports, and FTC will ordinarily accept the FDA determinations in its advertising actions. Examples are:

(a) Safety and efficacy claims for post-1962 over-the-counter drugs.

(b) Safety claims for post-1938 pre-1962 over-the-counter drugs which were handled as new drugs during that period and the efficacy claims for these drugs as validated by the NAS-NRC review.

(c) Claims for over-the-counter antibiotic preparations certified under the provisions of Section 507 of the Federal Food, Drug, and Cosmetic Act.

C. With respect to the safety and efficacy of prescription drugs the control of advertising as well as labeling is the responsibility of the FDA.

QUESTION AND ANSWER SESSION

MODERATOR: I would like to give you the maximum opportunity to ask questions and to have our gentlemen here respond.

Q: Mr. Hauser used the term "worthless" in his presentation. I take it that this means a drug may be useful or efficacious for a certain use, but not necessarily for all the uses that are perhaps in the labeling. I was wondering also if the FDA would determine comparative efficacy in its review. In other words, in the case of another drug of a like nature, whether the FDA would determine that one drug is more efficacious than another, and therefore one is more useful than the other, and one would be taken off the market, or recommended to be taken off.

A: My use of the term "worthless" was to designate a drug which is regarded as ineffective for any drug purpose. A useful drug is one for which there is evidence of effectiveness. On the question of comparative effectiveness, if a drug is a useful drug in the sense that its effectiveness and potential benefits outweigh its hazards, its marketing may be continued.

We are only concerned with comparative effectiveness to the extent that labeling or advertising makes claims comparing one drug with another falsely.

A: I'd like to elaborate on one point. Let's take a drug that may have four indications for use, three of which have the appraisal of "effective" from the Academy and the fourth one has the appraisal of either "ineffective" or only "possibly effective," which in the context of the order of judgments is probably ineffective.

I would hope that in our initial discussion with the manufacturers about such a drug the decision would be reached promptly to submit the supplement for the three claims for which efficacy has been recommended by the Academy, and that the fourth one be deleted from the labeling, and—if the matter is of sufficient interest to the firm—that it submit an NDA for the fourth indication. I think action of this sort can be taken promptly and quickly, and not cause the manufacturers a great disadvantage.

Q: Dr. Cannan spoke of more than 3,600 formulations. He did not speak about the number of products—"me too's"—that were referred to by others. I'd like to ask first if we can have any indications of how many products we're talking about, prescription and nonprescription, and what the dollar volume might be, some indication of how significant an impact all this may have.

cont'd on page 29



THE WATCH FOR HOUSEHOLD HAZARDS

A major function of the FDA's Bureau of Science is the use of its resources to protect the public from products that may be injurious or dangerous

to health. The FDC Act prohibits interstate commerce

in misbranded drugs or devices or adulterated cosmetics that may be injurious.

The Hazardous Substances Act requires appropriate labeling of substances

that may be injurious because of toxic or other harmful properties, and bans outright the sale of some substances considered too dangerous to be handled by the consumer or by children, regardless of labeling.

The Bureau of Science's Dermal Toxicity program, headed by Dr. Francis N. Marzulli, analyzes drugs, cosmetics, devices, or chemical substances which may become a part of them to determine injurious effects on the skin and its appendages (hair, nails), eyes, mucous membranes, and the body (systemic toxicity). The unit looks for effects of toxicity, irritation, sensitization, and carcinogenesis brought about by penetration, ingestion, or inhalation. It tests existing and new products or chemical substances that may become a part of them, some on complaints from the public or requests from FDA Districts. Its regulatory work is backed by a basic research program about hazards that may not be now known or recognized; unusual effects of certain substances on specific ethnic, age, sex, or other groups; the speeds with which such substances act; and the amount required to cause undesirable effects. The unit's dozen people make up two teams which study skin sensitization and eye toxicity and skin penetration.

DERMAL TOXICITY

HAZARDOUS SUBSTANCES

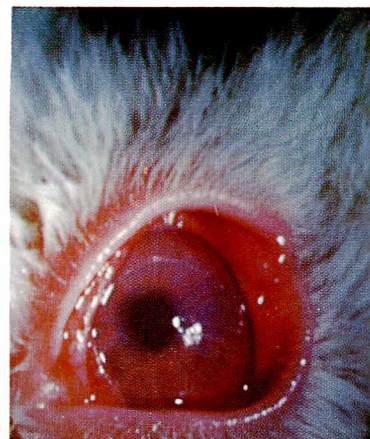
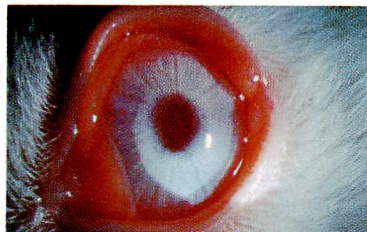
The Hazardous Substances program under Dr. E. W. Ligon, Jr., develops scientific data on products defined in the Hazardous Substances Act.

These are toxic, corrosive, irritant, strongly sensitizing, flammable, or pressurized articles which may cause injury or illness from home handling or use, including "reasonably foreseeable" ingestion by children. Excluded are "economic" poisons and certain other items regulated under acts administered by various agencies.

Hazardous substances are deemed misbranded unless appropriately labeled as the Act specifies, and some substances are banned outright as too dangerous for ordinary household use. Also banned are toys or other articles containing hazardous substances susceptible of access by a child to whom they are entrusted. The unit's staff of seven furnishes expertise for classifying or biological testing of up to a half million such products. The unit concentrates on the most urgent current problems. It also encourages the use of less harmful ingredients in products with a high incidence of human injury.

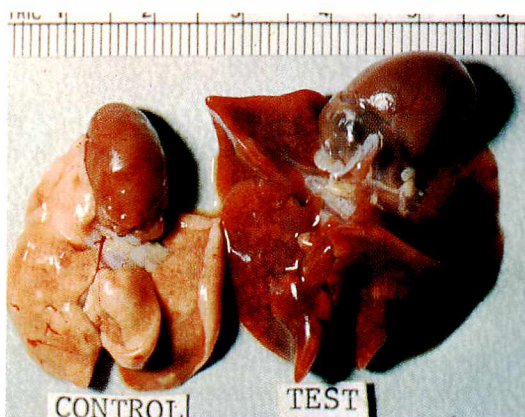
Below (left and right): A few years ago a commercial solvent called DMSO (dimethyl sulfoxide) was prematurely hailed as a wonder drug for many purposes and reached wide and unauthorized use in the medical field while still in the investigative stage. A finding that it caused nuclear sclerosis in dogs' eyes (see whitish growth in the lens of the beagle's eye), resulting in near-sightedness, brought a sharply curtailed use by mutual agreement between FDA and the maker. Scientist is shown using slit-lamp test to examine beagle's eye.

Below and right: Complaints that bubble bath capsule labeling failed to warn against squirting contents into eyes brought recommendations for more detailed instructions. Inflamed and normal eyes of rabbits show injury from product.



DERMAL TOXICITY

HAZARDOUS SUBSTANCES



Above: Damage to a hamster's mouth was caused by an explosion of a small "cracker-ball" resembling certain edible processed cereals. Cracker-ball fireworks sales are illegal in interstate commerce.

Center right: Flammability tests on an imported toy animal shows how quickly it could burst into flames and ignite the clothing of a child.



Above left: The photo shows normal rat lung (left) alongside one which has hemorrhaged from aspiration of petroleum distillate, an ingredient of many household products.



Above: Two pictures demonstrate a flash test of a flammable product being sprayed from a pressurized aerosol can and how flames could ignite any nearby combustible material.

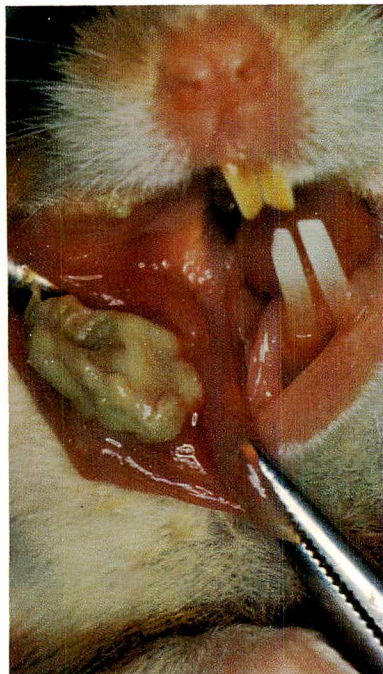
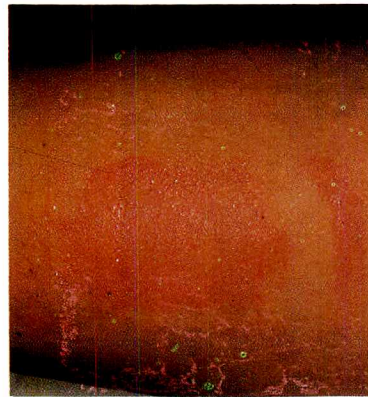


Left: A white mouse is shown with skin cancer caused by application of the synthetic compound DMBA in laboratory. The unit studies carcinogenic potential of chemicals, dyes, and other materials regularly applied to the skin.



Center: The unit has designed a contact lens to fit a rabbit's eye in its testing of possible toxicity from lens materials and the solutions used with them.

Below (left and right): Photos show human sensitization (allergic) responses to neomycin and benzocaine. Human "guinea pigs" are convicts who volunteered to undergo tests in an FDA contract with Dr. Howard Maibach of the University of California School of Medicine.

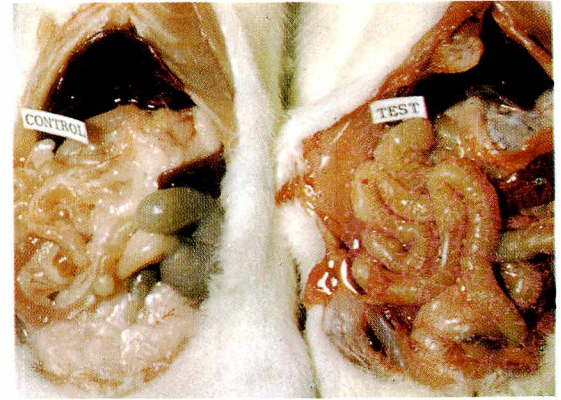


Above: The lesion in the hamster's cheek pouch resulted from deposit of a quantity of a granular laundry additive, which was removed and the cheek pouch washed out after 30 minutes. No medication was used.



Above: The gastrointestinal tract of a rat shows injury from ingestion of a rust-remover product. The stomach appears "cooked" and the intestines are abnormally discolored.

Below: One of the instruments used in FDA labs to carry out flammability tests focuses light rays in hot spots to find the flash point of a product.



Above: A normal rat's gastrointestinal tract (left) is shown opposite one which has become swollen and filled with fluid from ingestion of a soldering compound.

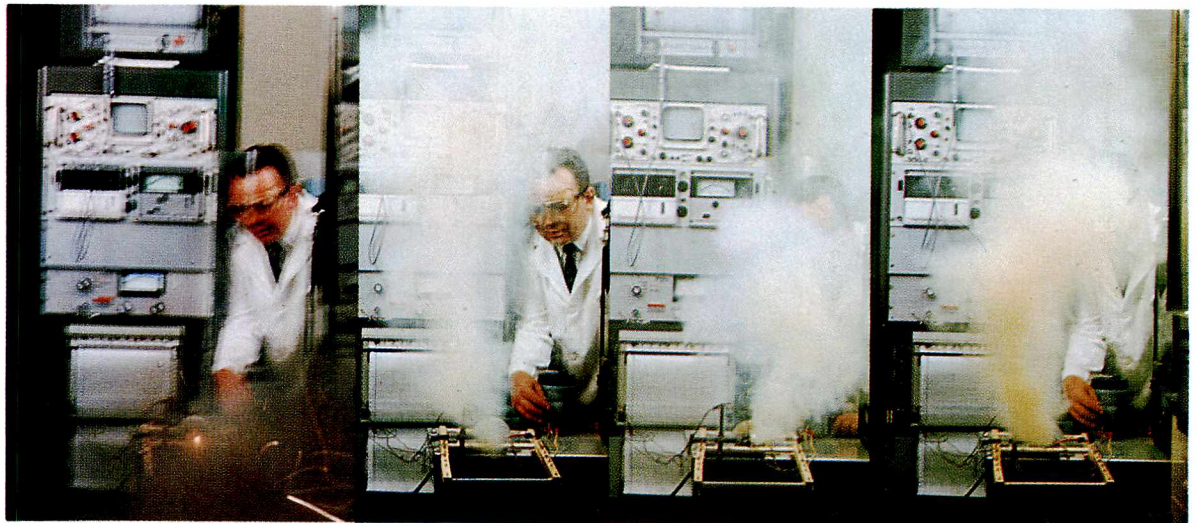
Below, in before and after photos: A real guinea pig is used in the Dermal Toxicity labs to demonstrate sensitization by DNCB (dinitrochlorobenzene). Both well-known sensitizers and chemicals suspected of being sensitizers undergo such tests.

Below and right: Photos show injuries to tissues under a woman's nails after she used a nail-hardener product. She and others complained to FDA and after patch tests confirmed its sensitization properties, the product was removed from the market.



DERMAL TOXICITY

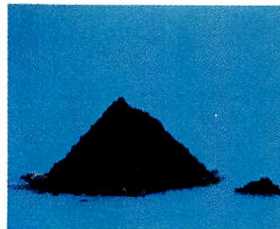
HAZARDOUS SUBSTANCES



At top: The sequence shows a controlled explosion of a toy "rocket" to measure the intensity and potential for injury.

At bottom center: The small pile of powder is the amount that can be legally used in a fireworks item and the large pile is the amount obtained from an illegal one seized by FDA.

Bottom right: The display shows the awesome size of some fireworks seized recently.



GMP's for the food industry

the case for regulations

In the 60 years that Federal law has been in effect to remove unclean or unwholesome food from interstate commerce, the Food and Drug Administration has sought in many ways to strengthen its enforcement of the statutes. From these actions have come higher standards of sanitation and a continuing improvement in methods of detecting filth, disease-bearing organisms, and toxic materials in food. These efforts coupled with refinements in the law itself should long since have assured cleanliness, wholesomeness, and safety of the Nation's food supply. Yet there are some food processors and distributors today who are still unaware of or who refuse to concern themselves with sanitary conditions and practices required of them to provide the protection to the consumer that the law demands. Why?

The law is couched in broadly general terms and says simply that a food shall not be contaminated nor prepared or handled in such a way that it may become contaminated when traded in interstate commerce. Congress has left determination of what constitutes contamination and the conditions likely to create contamination to the expertise of the FDA and its enforcement officials, supported by scientists trained in detection of filth in foods and using the most efficient methods that today's technology permits. This expertise has been refined and tested over the years in continuing research and in many legal actions.

Most businessmen in food processing and handling have long ago become fully aware of their obligations to provide a clean and wholesome product to the public and have made current good sanitation practices a vital and continuing part of their business operation. Some have found the requirements of modern day sanitation an almost intolerable addition to the other efforts they must make to stay in business. Some have plunged into the food business with little or no awareness of the painstaking diligence required to run a sanitary plant. And a few are ignorant of or sometimes scornful of these requirements and the legal and health consequences of passing on unwholesome food into the channels of interstate commerce.

The FDA believes all of these businessmen processing or handling foods can be significantly helped and kept up-to-date on current good manufacturing practices if the essential principles are written into a set of

regulations that will implement, interpret, and have much the effect of the law—that will tell the food processor when or where to go, to stop, or to exercise caution. These regulations will embody good manufacturing practices in sanitation, and the businessman will have before him a kind of bible which both he and his competitor must follow in fulfilling their obligation to assure the consumer of wholesome food.

The Agency has begun the first phase of this program on the basis that such regulations are both authorized and contemplated by the FDC Act. The first set of regulations, proposed on December 6, 1967, are general or "umbrella" rules that will apply to every company manufacturing, processing, shipping, handling, or storing any class of food in interstate commerce for human use. The second phase, dealing more in specifics, looks toward the adoption of appendices covering good manufacturing practices in various food industries. Although not required to do so by statute, FDA, as is customary, is soliciting comments from the food industry, consumers, and other interested persons on these GMP regulations.

FDA for some time has been issuing inspectional guidelines to its 17 Districts in several food programs such as smoked fish and *Salmonella* in nonfat dry milk. As inspectors gain experience in applying these, the Agency hopes to publish them soon in modified form as proposed appendices. Industry input to these existing guidelines also has been welcomed.

Just how necessary or desirable are GMP regulations? Consider some of these situations FDA Inspectors have encountered:

One plant proprietor, informed by an inspector that a urinal in a washroom had overflowed and backed up on the floor, requiring employees to wade through the filth, told the FDA man that he didn't see how this was pertinent since no food was processed in the washroom.

Another, shown by the inspector that fecal filth was entering food through insanitary employee practices as shown by findings in the food of *E. coli* and coliforms, micro-organisms that inhabit the intestinal tract, replied that the micro-organisms were killed by heat treatment farther down the line, so why worry? (The inspector asked him how he would like to have such fecal matter in his own food, even if they were killed.)

One firm's proprietor wondered what was wrong with his practice of allowing customers and other non-employees to wander around in the processing area in street clothes and without head coverings. Another found it hard to understand why he couldn't continue leaving cats in the establishment to take care of his rodent problem.

Employees, with an FDA Inspector watching, were unhesitant about bringing food into contact with their clothes, or arranging their hair without afterward sanitizing their hands. Official photographs taken by inspectors show employees smiling archly at the camera while performing acts in flagrant violation of good sanitary practices.

Some plant officials found it hard to believe that bacteria and other micro-organisms were present in thoroughly cooked food until shown by the inspector that insanitary practices took place after the cooking.

Here are some examples, taken from FDA case files, of representative offenses against good sanitation and employee practices in various food industries in several parts of the country. In most cases the offenders have been cited for violations and successfully prosecuted or have been enjoined by the courts from further violations. In some cases both of these actions have been taken, as well as seizures of contaminated products. Large quantities of food products also were voluntarily destroyed by some of the firms as a result of findings by FDA investigators.

On Memorial Day in 1966 a group of people attended a Bar Mitzvah ceremony in New Jersey. A few hours afterward 34 in the group were stricken with febrile gastroenteritis. The Public Health Service's Communicable Disease Center investigated this food poisoning and pinpointed the source as smoked whitefish, based on stool cultures of 11 of the stricken persons and analysis of samples of the food furnished by the host. PHS gathered evidence of 12 separate poisoning outbreaks on that and the following day, involving more than 300 persons in the New York and New Jersey areas and Philadelphia—all linked to smoked whitefish. The culprit was *Salmonella* of the *Java* serotype, and the contaminated fish all was traced to a New York firm specializing in processing smoked fish of various kinds.

FDA's New York District inspected this firm and two other smoked fish processing firms in the area. The inspectors found inadequately cleaned plants and equipment; greasy encrustations on ovens, smoke racks, utensils, and other equipment; and accumulations of fish scales and residue and other filth on fixtures, floors, equipment, worktables, and containers. In one plant they found signs of rodents, in another dog feces. Building openings permitted access by rodents and flies. They noted employees handling nonsanitized objects, then failing to sanitize their hands. They found overflowing urinals, pieces of rotten fish in processing areas, uncov-

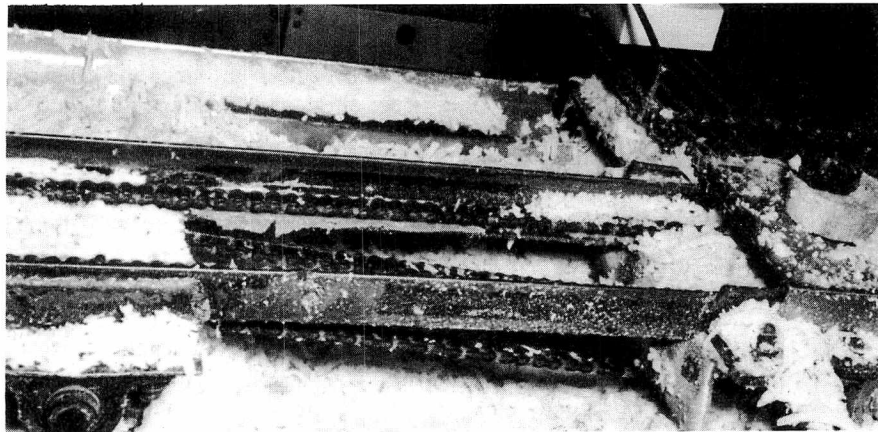
ered garbage cans, equipment that was not sanitized after use, and, in one plant, a live rat. Employees in one plant were noted wiping their noses with their hands without sanitizing hands afterward, and spitting on the floor. An employee at one plant was observed eating fish constantly as he smoked them, after handling unsanitized equipment. Hands and equipment were rinsed in all-purpose containers and wiped with all-purpose rags. Samples of smoked butterfish, taken at the plant originally linked to the poisonings, revealed *Salmonella*.

In July 1967 New York District Inspectors called at a firm in New York City which manufactures Chinese noodles, pastry skins for egg rolls and won tons, and Chinese spaghetti. The plant had a history of insanitation, but conditions had grown worse. Inspectors found live insects in raw material storage areas, heavy dust accumulations throughout, two cats on the premises, improper employee practices in handling of in-process and finished products, equipment and utensils encrusted with dough and grease, no use of soap or sanitizing solutions, and disregard for good employee sanitation practices. The front door was left open and nonemployees were allowed in the processing area. Cans containing a mixture of water and eggs were open and had been left standing for 6 hours at room temperature, allowing the mix to decompose. A sample of the egg-water mix and a sample of won ton skins collected from interstate commerce were found with high coliform counts and bacterial plate counts.

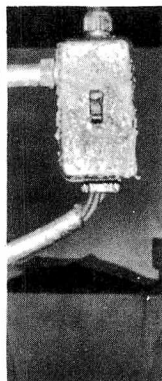
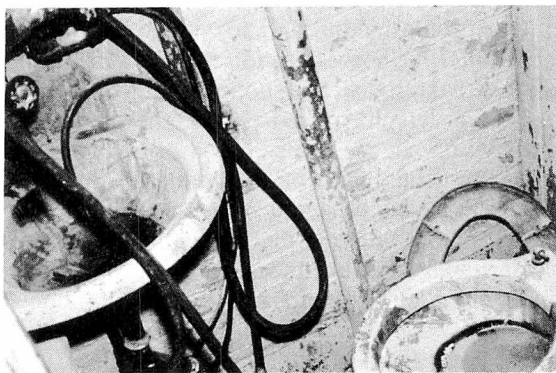
In June, July, and August 1966 Cincinnati District Inspectors visited an Indiana firm processing, packing, and distributing nonfat dry milk and products containing it. The old building was in a poor state of repair, allowing entry by rodents and birds. A live bird and rodent and bird excreta droppings were found in raw material or storage areas, some on bags of raw material. About 50 dead insects were noted. Caked, crusted material was found in and on processing equipment. Bags of raw material were covered with dust accumulations which were not brushed away before use. Pond water used to cool fluid milk in containers was later found to contain *Salmonella*. Samples of various filth collected in the processing area revealed *Salmonella* contamination.

Buffalo District Inspectors checking a Pennsylvania firm in May 1967 which makes frozen cream and fruit pies, cakes, and frozen bread dough found food materials still left on processing equipment after cleanup by employees. Other findings included a dead mouse, a dead rat, and rodent excreta pellets in the storage room. Moths were found in a quantity of nuts. Product mixtures had been stored at excessively high temperatures.

In August 1966 the Cincinnati District inspected an Ohio baking firm which bakes bread, buns, sweet rolls, and other products for sale to hotels, restaurants, and institutions. The FDA men found numerous beetles of three types in adult, larva, and pupa form, plus frag-



Some examples of insanitary conditions or poor employee practices are shown in these official FDA photos taken during inspections of food processing or storage establishments. Above left, stacked bags of beans in a warehouse were sprinkled with sodium fluosilicate, a rodenticide, and later analysis showed the product to be contaminated with this deadly poison. Above right, residue built up on shredding machinery in a potato processing plant and remained several hours, inviting bacterial growth. At right, plant's laxity in keeping its restroom in sanitary condition is apparent. Below right, access of rodents to stored bags of pretzels in a distributor warehouse is confirmed by presence of excreta pellets. Below center, frequently used electric power switch shows food residue from hands of employee. Below left, employee moving a piece of dough carelessly brings it into contact with his clothes.



ments of beetles, in and around mixing and conveying equipment. More beetles, along with roaches and flies, were found in the fermentation room and in other processing areas. An improperly fitted door allowed ingress of flies. The plant's use of mineral oil for lubrication of processing machinery appeared to be above tolerance. Analysis of a sample from one of the products delivered to a hospital in Kentucky disclosed one beetle and several fragments. Inspections in previous years had disclosed insect infestation in the plant and other violations.

In March 1967 Denver District Inspectors visited an Idaho firm which processed frozen french fried and hashed brown potatoes and frozen whole peeled potatoes. They found sour-smelling and discolored potato residue in and on processing and conveying equipment along the production line, paint flaking off equipment

over the line, and unhygienic practices by processing employees. Earlier inspections had indicated that equipment and utensils were of poor design or materials for keeping clean and, although the firm had replaced some equipment, there were still problems with cleaning older equipment. The District in past inspections had collected official samples showing excessive counts of *E. coli*, coliforms, and total bacteria.

In January 1967 inspectors from the Cincinnati District visited an Ohio firm engaged in wholesale distribution of pretzels, popping corn, and other snack items. All the doors of the warehouse area had cracks that would admit rodents. The inspectors found rodent excreta pellets on the floors of three of the warehouse area walls, under stacks of cases of pretzels and popcorn, and in the cases themselves. Numerous bags of pretzels and popcorn inside the cases had been gnawed

by rodents and some of the contents gnawed or removed. Holes had been drilled by insects in other bags and the products contained live and dead beetles in larva or adult form. The firm had been cited at a hearing in July 1966 and had promised to make improvements by cleaning up debris which offered harborage to rodents and by rodent-proofing the building, but subsequent inspections showed little improvement.

In March and May 1966 Atlanta District inspected a mill in North Carolina manufacturing cornmeal, cornmeal mix, and animal feeds. They saw a live rat running into a metal chute where corn was dumped from trucks upon purchase by the mill and spotted more than a dozen structural defects in the old four-story building that would admit rodents, plus broken window panes permitting access by birds. They noted accumulations of debris offering harborage for rodents. In the manufacturing area screens and hoppers, into which grain was fed, were left uncovered part of the time.

In practically all the foregoing cases involving rodent contamination there runs one continuing, ironic theme: each time an inspector found rodents or rodent signs in an establishment, before his departure he urged the owner or manager to take measures to make his building rodentproof and to eliminate conditions conducive to rodent activity by improving storage methods, cleaning up debris, etc. In case after case and time after time the proprietor would promise these improvements. Then he would stress that he had begun to use rodenticides in greater amounts, was hiring a commercial exterminator, was asking the exterminator to increase the frequency of visits, or was switching from one exterminator to another. One firm official said he had now hired two exterminating firms, each visiting on alternate weeks. But not one of the firms solved its rat problem this way.

Such attitudes on the part of some of these businessmen are typical of the kind of thinking that horrified FDA officials a few years earlier.

In the late 1950's and early 1960's FDA's Dallas District, inspecting several firms handling or storing beans, grains, meals and flours, and animal and poultry feeds in parts of Texas and Arkansas, found that sodium fluoroacetate, a deadly poison for which there was no known antidote, was being used on the premises of these firms in such a way that the food might become contaminated with the poison. The careless use of the highly toxic rodenticide was traced to a single firm in Texas which was furnishing exterminating services to all the handling and storage firms. The poison, known commercially as "1080," was placed in flimsy paper or other unanchored containers so close to stored foods that there was a danger it might get into the food materials, through spillage or otherwise.

The FDA had already encountered the problem of rodenticides in California. In inspections of a number of warehouses in that State during the winter and spring of 1956 the San Francisco District found that a

related poison, sodium fluosilicate, had been sprinkled by these firms on thousands of 100-pound bags of beans in storage. Further checks indicated the practices had been going on since the previous fall, and thousands of bags of beans had already been shipped interstate and to ports in Cuba, Puerto Rico, and Costa Rica. Samplings showed poisoning of beans and bag materials. Quick and massive action was necessary. FDA Districts in several parts of the country were alerted to shipments sent to cities in their areas and wholesale seizures and embargoes involving thousands upon thousands of bags were ordered.

What are some of the advantages of GMP regulations? They will let the businessman know what is required of him—upkeep and cleanliness of buildings and equipment, of qualifications of employees and other matters to be covered generally and specifically. They will standardize principles or checklists to be followed by the several FDA Districts for assurance that there are no inequitable applications of requirements arising from differences in individuals, geography, and other factors. They will raise sanitary and quality standards of food and assure the consumer that good manufacturing practices are being followed by all firms shipping food in interstate commerce. State and local officials will be able to benefit from knowledge of the GMP regulations in their surveillance over food shipped only in intrastate commerce.

It has been argued that GMP regulations are unnecessary in the already overregulated food industry and that expenses of compliance to manufacturers will result in higher food prices. It has also been said that regulations will be so general as to be meaningless. It has been held that inability to comply will drive many firms out of business.

To the argument that they are unnecessary, it should be said that the regulations, to the extent that they are applicable, will do no more than codify and standardize FDA practices which exist, or will, or should exist. To the consumer, the price he pays for the wholesomeness of his food is the very best food bargain he can get for his money.

To the argument that GMP regulations will be so general as to be meaningless, the FDA case histories described in this article offer ample testimony that some food processors at present have little conception of the sanitation practices the law requires of them and any regulations at all would be better than none.

To the argument that the burden of compliance may drive some food manufacturers out of business, it can only be said that in this age the consumer has entrusted the function of processing his food to those who are, or should be, more qualified to do so than the consumer himself. In return the consumer has every right to expect, and the FDA to assure, that this food supply will be clean and wholesome. ■

DRUG EFFICACY REVIEW *cont'd from page 19*

A: I am Earl Grove, National Academy of Sciences, with the Drug Efficacy Study.

We have logged in, as Dr. Cannan said, some 3,600 preparations. That actually means we have logged in 2,824 sets of preparations: maybe three or four tablet sizes, or perhaps a tablet and a syrup under one logging system. It's the same drug, but perhaps represents two, three, four, or five preparations. So we've logged in 2,824 sets from the 237 firms. But this represents 3,640 individual preparations. Is that clear?

A: Our estimate is that for every drug under review by the Academy and covered by an NDA there is an average of five other identical drug products on the market—produced by other firms without an NDA.

We have no base for determining the accurate ratio. We have estimated it as five to one. If you take the roughly 3,000 drugs the Academy is reviewing and multiply by five, you get 15,000 additional products.

We have no estimate as to what proportion these 17,000 or 18,000 total drugs represent of the financial transactions handled by the pharmaceutical industry.

A: One of the outcomes of the publication of these determinations by the FDA in the *Federal Register* will be the identity, in effect, of not only the firm making the particular drug which was reviewed, but all other firms which make similar products. Probably the finite answer to your question is 2 to 3 years away.

Q: What's the future status of the digestive enzymes?

A: We have received no report on this class of drugs.

A: We do not know in advance the drugs being sent to us. Predicting when the analgesics or the cardiovasculars, or whatever will come up is not possible.

A: Rather than getting each drug as it clears the panel chairman or the responsible panel—there are multiple panels involved—we have asked that the Academy collect in one group all drugs falling in a particular category, so that they can be considered at the same time. Our notice of when a group is coming over is very short—very short indeed.

Q: Did the review consider only effective NDA's or did it also include "me too" drugs and non-NDA's?

A: The review by the Academy considered only those drugs currently under NDA's for the 1938 to 1962 period. It did not consider any drugs in the so-called "me too," non-NDA category for that period, nor did it request information from firms other than those holding NDA's.

Q: Did I understand from Dr. Cannan that the report of the NAS group would be released intact? And if so, when will this report on rutin and various other products be released?

A: The report will be released intact. We feel that we

must transmit by letter the reports to the specific firms involved prior to the meeting. We anticipate mailing the reports on the bioflavonoids today so that the firm itself will have copies within the very near future.

This process of mailing the report to the firms places it at that point in the public domain, so that it would be available to other parties at the subsequent meeting scheduled January 31 for this category.

Q: What proportion of the drugs, both prescription and nonprescription, will ultimately be affected by the NAS-NRC review?

A: Substantially all drugs marketed from 1938 through 1962 will require some modification in the labeling claims, we think. That doesn't mean we think that any substantial number of them will be completely ineffective, but we think that the labeling of all of them will need updating as a result of this NAS-NRC review.

Q: How will the NAS reports be released by the FDA to the public and to the press?

A: They will be on view in the FDA public information office when they are received from the Bureau of Medicine, after the letters are sent.

Q: It appears to me that these reports are going to be released to only those who have NDA preparations. What about those who haven't filed?

A: Of course, we have to provide the original NDA holder with copies of the report in direct correspondence. As soon as this is done, then the report is in the public domain. It may be provided by our public information office. We will have copies available for the subsequent meeting scheduled to discuss a particular class of drugs, so that they may be obtained at the time of the meeting.

A: If we had a list of all the "me too" manufacturers for a particular drug product, it would be possible to send letters including the statements to them. Such a list does not exist. For this reason I would like to outline briefly the four steps involved which I do think provide an adequate attempt at notification of the other manufacturers.

When the Academy recommendations are received at FDA, they are then reviewed internally and transmitted directly to the manufacturers involved with the NDA's. At the same time, there will be prepared for publication in the *Federal Register* an announcement of a proposed meeting to discuss FDA's position on the National Academy recommendations.

The specific drug area that is to be discussed will be in the *Federal Register* statement. I think it would be possible to list in the same *Federal Register* statement the drugs that would be considered by name, so that any manufacturer with a comparable drug could make plans to attend the meeting.

Q: Will the manufacturer be permitted to request a copy of the report?

A: As soon as it is distributed by mail to the NDA holders, it is open to any other manufacturer.

A: The information then would be disseminated not only through the *Federal Register*, but it will also go to the press, as well as be on view. And as the NDA Approval List has been carried, and the Recall List has been carried, I assume that the associations in their newsletters and the trade and industrial press itself will further convey that information to all manufacturers.

Q: Suppose a so-called “me too” manufacturer wants to come in and present evidence, or proof—and may be capable of doing it. He will not be familiar with what the report is and will be unable to properly protect his interests unless he gets a copy of it or the full report is sent out.

A: Well, the wording of the *Federal Register* statement for the future, I think, would include three major points: the acknowledgment of receipt of Academy recommendations on such-and-such drugs; an invitation to meet to discuss the Agency proposal for action in this area; and the statement that anyone wishing a copy of the recommendations may write for it.

Q: If there are certain deficiencies for a drug which need correction on a clinical or experimental basis and the holder of the NDA furnishes this information and labeling is then properly corrected, will this information be usable by the “me too” manufacturer? In other words—can he ride the coattails of the NDA holder? Or must he, on his own basis, produce scientific evidence to support the efficacy?

A: We would consider a general breakdown in two areas here. When I indicated that some applications would require essentially an original or supplemental New Drug Application—that category of application is independent. Each manufacturer has to provide his own information. There is no ready access from one application to the other, for manufacturers.

The other categories of action—“not new” drugs, and the abbreviated NDA to some extent—will concern themselves with drugs for which there is good evidence for efficacy. And in those particular cases the type of information required is not the type that you mentioned in your question.

To put it in another light: For the “not new” drug category, obviously, and for the abbreviated NDA category as well, there would be essentially no privileged information of the type that you describe. That type of application, I think, will be handled almost exclusively by the regular New Drug Application process.

Q: Is there a possibility that a withdrawal of an approval for a drug that is useful but there are various unsupported claims made for it, is it possible that with-

drawal of an application, or approved application, could be used as a club to prevent a manufacturer from litigating claims which he believes in, which would ordinarily be handled by seizure action and litigation in the courts?

A: There is no way we can keep anyone from litigating any question he wants to. What we are trying to do here is to arrive at an administrative procedure for bringing these medical judgments into the labeling of drugs in the most rapid way possible. If we have to litigate, we'll use, of course, any charge that is available to us, including false and misleading claim charges, as well as failure to have New Drug Application.

But we don't think we're using anything to prevent litigation. At the same time, we are trying to encourage a situation in which the needed reforms in the promotion of these drugs are not delayed interminably by litigation.

Q: During the last couple of weeks we have seen newspaper stories to the effect that a large number—I believe the number 300 has been mentioned—of drugs will be removed from the market. A while ago, the opinion was expressed that probably some changes in labeling will be required for the vast majority of the drugs under review. Dr. Cannan, in his remarks, said, as I recall, that less than a hundred reports have been transmitted to FDA thus far. Maybe the number is 21. He also said no one could draw any statistical conclusions from the few reports already submitted.

Now, frankly, I think that manufacturers, and the medical profession, can express some puzzlement as to these general conclusions that responsible Government officials are making. Either they have access to the reports before they have been transmitted, or else they are merely guessing. If it is the latter, I would question the desirability of doing that.

Manufacturers generally, and I think all of the private sector affected by this study, are just as interested in being responsible citizens as most everybody else. And I think all of us appreciate Dr. Cannan's observation that industry has cooperated in the work of the Academy. I think FDA must recognize that, too.

A: There has been a very good relationship between the FDA and the Academy regarding the security of the information they have been working with. The estimate of approximately 10 percent of the numbers of drugs submitted to the Academy as being probably “ineffective” was made on the basis of experience by a number of doctors—conversations that have been had over a number of years. The 10 percent estimate doesn't seem to be very new.

To the substance of your question, there has been no advance information from the Academy to us to give us a definitive number of “ineffective” drugs.

A: These figures, as they have been quoted, were very carefully qualified as being mere “guesstimates.”

It is always necessary to make some assumptions in setting up a reviewing process and to decide roughly how many are in this category or that category, recognizing full well that the estimates will undoubtedly change. But they are still the best estimates we can make at this time.

I base my estimate on the experience with reviewing existing labeling, plus what I know about the problem of bringing this labeling that was approved—some of it up to 25 years ago—into line with current medical thinking. For that reason I estimate that most of the drugs will require some revision in their labeling.

Q: Is there any estimated date by which the reports on the full range of drugs under review might be expected?

A: We hope to receive all the reports from the Academy by the June 30 deadline. They are coming in, I think, in packages of a hundred.

Q: With regard to the possibility that you expect a 3-year period during which the Task Force of the Bureau of Medicine may implement the results of the efficacy study, could you give us an estimate of when you would first expect to have something coming out of your Task Force? And if so, what categories of drugs do you think you may be dealing with first?

A: We may be overly hopeful, but I believe that we will have what we consider the bare bones of appropriate labeling for all the materials which the Academy transmits to us by October 1 of this year. Where our decision is that a particular drug is no longer a “new” drug, that action may be implemented immediately.

We are weighing the time limits for new information that must be provided to us to support certain claims which the Academy feels are not soundly based. The time period here runs between six months and a year.

Following this initial receipt of the bioflavonoid group, you may expect almost immediate action on drugs which the Academy feels do not have sufficient evidence to demonstrate efficacy.

About new drugs—requirements would hopefully be published by the end of this year. The slow process of accumulating additional information on NDA's is likely to go on for at least another year.

Q: Is there any indication of how often industry was called in by the reviewing panels to supply additional data? As I recall, the review was based primarily on efficacy. I notice you express concern about toxicity, side effects, and so on.

A: I know in our discussions with Dr. Cannan there was every indication that they were getting constant and continued support from industry, and the affected companies were submitting all the data they could to support claims for their drugs.

There has been no evidence at all that full industry

cooperation was not the order of the day. The Academy was continually open to all submissions throughout this past year and a half.

A: In regard to the second question, the Academy's comments are, on the surface, efficacy only. However, the Academy may—and informal conversation has suggested that it will in some cases—make certain comments about efficacy that have a safety overtone.

In other words, if a very old, old drug is not as efficacious for the treatment of this particular condition as others that are currently on the market, the Academy feels that this type of comment is appropriate for them to transmit to us.

As for the safety question of a drug which may not be biologically equivalent—that is our decision to make.

Q: I wonder if FDA would be willing to outline its plans as to how compliance will be obtained by manufacturers who do not have an NDA. I understand that there are about five “me too” manufacturers for every one that has an NDA. Do you have a plan for checking out this category of manufacturers for compliance?

A: Part of the plans for Agency growth over the next several years is a stronger emphasis on field activities—more emphasis on more rapid inspections of all the firms in the country. We do not plan to write specifically to each of these firms, but we consider this to be an appropriate portion of the District inspectional task. FDA District personnel, with their copy of the same statement that appears in the *Federal Register*, would review each firm that they visit during the course of the year to see whether that firm is manufacturing products listed in the statement. If they are, is the product being marketed—if not a “new” drug—with an approved label? If it requires the submission of an abbreviated NDA, has the firm provided this information?

A: We traced step-by-step how we propose to effect compliance—with some groups classifying a drug under specific conditions and under specific labelings as a “not new” drug, requiring the abbreviated form for others, and a complete form for yet others. This will give all the “me too” operators who do not now have New Drug Applications but who will require them, an opportunity to come into compliance, to have drugs on the market that would be classified as “not new” drugs with limited labeling. They would have an opportunity to pull back their labeling to comply with that statement of policy which will be in the *Federal Register*.

A: We have plans for an expanded field force, and sample collection program at the retail pharmacy level, which would give us a better idea in the months ahead of the universe of drugs available. And we have, of course, an open-door policy to all firms to sit down and counsel with us. We would welcome any continued and future comments you have. Thank you.

ATLANTA DISTRICT Because of poor housekeeping conditions and rodent-contaminated foodstuffs, a North Carolina wholesale grocery and its president were fined \$700 each on December 7. S. E. Hauser, Inc., and Harry L. Hauser, High Point, entered guilty pleas to a two-count criminal information. The judge suspended the fines for 3 years on condition that the defendants come into compliance with FDA regulations.

Coble Dairy Products Cooperative, Inc., Anderson, S. C., was fined \$500 on December 18 for selling misbranded "orange juice." The Florida Citrus Commission initiated the action when it reported to FDA its investigation of a product labeled "Coble Pure Florida Indian River Orange Juice." The product was not orange juice as labeled, since it contained somewhat less than 60 percent orange juice and was diluted with water and added sodium.

BALTIMORE DISTRICT Twenty-one tons of decomposed frozen eggs were buried in a Baltimore, Md., dump on December 15. The eggs were shipped by Olson Bros., Inc., La Habra, Calif., and were seized in Landover, Md. The court ordered the claimant to pay \$1,922 for storage and \$56 court costs.

BOSTON DISTRICT A drug firm and its president consented to a Decree of Permanent Injunction on December 11. Cowley Pharmaceutical, Inc., Auburn, Mass., and Benjamin C. Cowley, had been charged with manufacturing and selling misbranded and adulterated drugs in interstate commerce. The drugs were violative because: their strength and quality did not meet U.S.P. or N.F. standards; their labeling did not correctly indicate the quantity; and their labeling lacked adequate disclosure information. The consent decree enjoined the firm from shipping adulterated and misbranded drugs; enjoined the firm from shipping any drugs in interstate commerce until it establishes adequate methods and controls in conformity with good manufacturing practices; and ordered all drugs on hand to be assayed and then either brought into compliance with the law or destroyed.

BUFFALO DISTRICT A lot of *Salmonella*-contaminated frozen whole eggs was seized in Buffalo, N.Y., on December 28. The lot consisted of 1,988 cans, valued at approximately \$10,000, remaining from an original shipment of 2,000 30-pound cans made by Brasher Brothers, Inc., Burbank, Calif. Of the 12 cans distributed before seizure, 10 were voluntarily destroyed.

CHICAGO DISTRICT More than \$153,000 worth of "Rynatuss," a prescription decongestant drug, was de-

stroyed recently by Neisler Labs, Inc., Decatur, Ill. The company found that the product was below its standards in one active ingredient and voluntarily recalled eight lots from nationwide distribution. The drugs were buried at a dump.

Brewer's yeast defiled by rodents and insects was voluntarily destroyed by Mississippi Avenue Warehouse, Division of Aaron Ferer & Sons, Inc., East St. Louis, Ill., after an FDA Inspector noted the contamination. The two lots were valued at \$1,775.

CINCINNATI DISTRICT Although an \$18,000 fine against the C. M. Bundy Co., Cincinnati, Ohio, was reduced to \$400 in the understanding that the firm would make improvements (see December-January FDA PAPERS), it has *not* made the improvements. The firm indicated to the court that it would move to new quarters in October. The fine was lowered on September 14, but the firm is still in the same quarters and is still producing drugs which are in violation of the Food, Drug, and Cosmetic Act. The firm has finished one recall and is conducting two others.

District Director T. C. Maraviglia is a member of the Cincinnati Consumer Affairs Council, which held its first meeting in November. FDA is the only Federal agency represented. The Council was formed under the auspices of the Better Business Bureau to develop, broaden, and strengthen continuing dialogue and to promote and improve understanding between consumers, government, and business concerning business practices. The Council includes representatives from education, labor, religious, civic, business, government, and women's groups.

DALLAS DISTRICT The third Texas sanitation workshop for food warehousemen was held in San Antonio on December 5. It made a total of five such workshops in 1967 in Arkansas, Oklahoma, and Texas. Judging from the number of criminal prosecutions of food warehousing firms in the three States in recent years, this educational approach to consumer protection is needed. A fourth Texas sanitation workshop, cosponsored as before by the Texas Wholesale Grocers Association, will be held in Lubbock on April 2.

DENVER DISTRICT Approximately 13,000 "Fem-icin" tablets were seized in Denver, Colo., in December because the labeling did not contain warnings of possible kidney damage after prolonged use. The tablets were manufactured by Thayer Laboratories, Inc., Metuchen, N. J.

Due to adulteration, approximately 47,000 "Sanestro" tablets were seized at Sandia Pharmaceuticals, Albu-

querque, N. Mex., in December. FDA charged that the strength of the tablets differs from that they purported to possess.

DETROIT DISTRICT Rusty, swelled cans of sardines were kept off the market in the fall through cooperative efforts of Detroit and New York Districts and Detroit Department of Health. The sardines in salt were imported from Sicily and held in warehouses in Detroit and New York City. The Detroit Health Department found five cases of the defective cans and held the shipment while Detroit District analyzed the contents. When the results revealed decomposition, the city had the entire lot burned. New York District, which was alerted that part of the original lot of sardines was stored in Brooklyn, found a second brand of sardines in salt which were in rusty, swelled cans.

The death of a Toledo, Ohio, resident after he used a Canadian cancer serum is under investigation. The Toledo Health Department reported the incident to the District. The victim's symptoms suggested lockjaw, and examination of the remaining serum from a Windsor, Ontario, clinic revealed *Clostridium tetani* and other organisms. District Inspectors investigated and reported their results to the Canadian Department of National Health and Welfare. It has collected samples and placed all stocks of the serum under seizure pending analysis.

KANSAS CITY DISTRICT Adulterated and misbranded frozen dressed whiting, valued at \$2,556, were seized at Kroger Co., Hazelwood, Mo., and Merchants Refrigerating Co., St. Louis, Mo., on December 5. The product, weighing 17,750 pounds, was partially eviscerated whiting instead of dressed whole whiting. The labeling falsely bore statements such as "pan ready," "thoroughly cleaned," and "ready to cook and serve."

Special holiday packs of jellies and preserves, valued at approximately \$450, were seized at Santa Claus Industries, No. 1 Gift Quality Avenue, Waterloo, Iowa, on December 12. The 4,968 jars had inconspicuous labeling. The distributor failed to heed a warning FDA gave it a year ago on similar labeling.

LOS ANGELES DISTRICT "Incredible Edibles" and "Gobblydegook" novelty items for children were voluntarily relabeled by the manufacturer, Mattel, Inc., City of Industry, Calif., to warn against use by diabetics. The materials are food mixtures which can be formed into various shapes, such as animals, and then eaten. They contain sorbitol, glycerine, vegetable gums, and starches, and were labeled as "Sugarless." Since the items could harm a diabetic child, the label statement was misleading. Wholesale and retail stocks were relabeled with appropriate warning statements.

Misbranded fresh lemonade was seized at Foremost Foods, Phoenix, Ariz., recently. Shipped from an Orange, Calif., manufacturer, the 1,650 half-pint containers of lemonade were falsely labeled as enriched with vitamin C.

MINNEAPOLIS DISTRICT Due to adulteration with *Pseudomonas aeruginosa*, several lots of hospital lotion shipped by Badger Laboratories, Jackson, Wis., were embargoed by the State of Massachusetts. District Inspectors found that the source of contamination was well water. The company voluntarily recalled several lots of the lotion.

Frozen ready to fry breaded shrimp pieces were seized in Green Bay, Wis., on December 28 due to adulteration with *E. coli*, staphylococci, and a high total bacteria count. The shipper of the 200 cases was Morgan City Freezer & Cold Storage, Morgan City, La.

NEW YORK DISTRICT The District held a sanitation workshop for the Chinese noodle industry on December 7. Government and industry representatives participated in the program, which included films on bacteriological contamination, an illustrated discussion on eggs and egg handling by a USDA representative, and a tour of the District Office. Eggs are an important ingredient of Chinese noodles and make the product very susceptible to bacterial contamination.

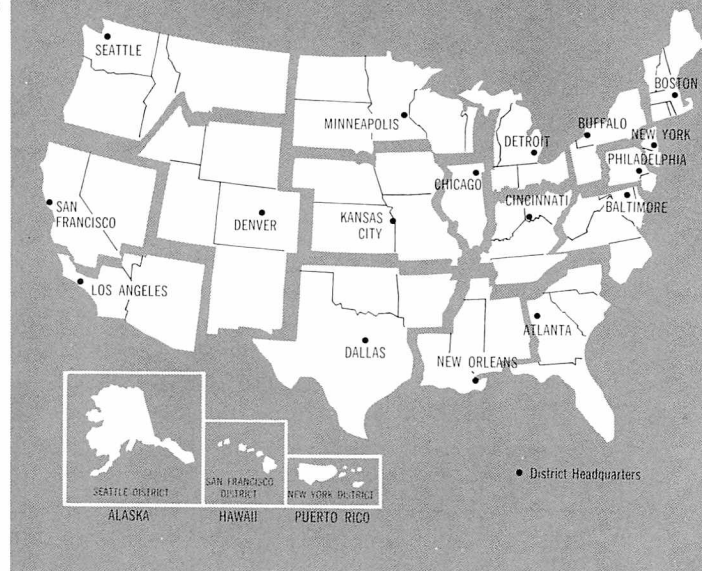
Canadian fisheries officials and the District worked out an agreement in December on importation of whitefish from Canada into the United States. Canada's Department of Fisheries proposed that shipments of whitefish, which are subject to parasitic infestation, that are bound for the United States be sealed immediately after inspection by Canadian authorities. The shipments would then be passed through Canadian and U.S. Customs without sampling for analysis. The District agreed to coordinate with the U.S. Customs officials in its jurisdiction to insure that the arrangement is carried out smoothly.

NEW ORLEANS DISTRICT Two groceries were fined in December because of rodent contamination. Clayton-Brown Co., Memphis, Tenn., a wholesale grocery, was fined \$1,250 for storage of food under insanitary conditions. All counts against an individual were dismissed. United Cash Grocery, New Orleans, La., a food wholesaler, was fined the maximum of \$2,000 on two counts. The judge said he was sorry that he could not assess a higher fine in view of the serious rodent infestation in the warehouse. He suggested that FDA maintain surveillance over the grocery's operation in its new location and over the future performance of an individual against whom charges had been dismissed.

A regulatory training course on medicated feeds was held for State officials December 5-8 at Jackson, Miss. The District and FDA's Office of Legislative and Governmental Services sponsored the course for officials from Alabama, Louisiana, Mississippi, and Tennessee. Some of the participating States may take over major obligations for inspecting and controlling medicated feed manufacturers in their areas.

PHILADELPHIA DISTRICT A chemical distributing firm was investigated because of alleged manufacture and sale of LSD and misbranding of hazardous chemicals. As a followup to a congressional complaint regarding serious injuries to teenagers, the District investigated M & B Laboratories, Cornwells Heights, Pa. The firm distributes do-it-yourself explosive and fireworks kits and chemicals for home chemistry sets. Seizure of approximately 300 bottles of repackaged chemicals has been recommended because of lack of mandatory warnings. Two Temple University students who operate the firm were arrested in November by BDAC Agents because of the firm's manufacture and sale of LSD and ingredients for making LSD.

Due to mold, nine drums of thyroid powder were seized in December at Newark, N. J. A lot of 13 drums was originally consigned to Richlyn Laboratories, Philadelphia, Pa., which discovered mold when it granulated a portion of the lot. The firm returned the remaining powder to the Newark distributor where it was later seized. The four drums of the granulated portion which Richlyn Laboratories returned to the manufacturer in Kankakee, Ill., were also seized by FDA in December.



SEATTLE DISTRICT Due to rodent excreta pellets, 116,160 pounds of bulk wheat, valued at \$4,500, were seized at Spokane, Wash., on December 11.

Decomposed pink salmon packed by Berman Packing Co., Ninilchik, Alaska, is being recalled voluntarily in cooperation with the National Canners Association. The NCA previously detained the 3,792 1-pound tins, but they were inadvertently distributed.

Because of metal fragments, approximately half of a 20,000-pound shipment of chocolate coating is being destroyed voluntarily by the manufacturer, Guittard Chocolate Co., San Francisco, Calif. District analysis of chocolate-coated peanut bars made with the product show numerous metal fragments, and seizure of stocks is being recommended.

FDA DISTRICT OFFICES

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

BALTIMORE 900 Madison Avenue
Baltimore, Maryland 21201

BOSTON 585 Commercial Street
Boston, Massachusetts 02109

BUFFALO 599 Delaware Avenue
Buffalo, New York 14202

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

CINCINNATI 1141 Central Parkway
Cincinnati, Ohio 45202

DALLAS 3032 Bryan Street
Dallas, Texas 75204

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

DETROIT 1560 E. Jefferson Avenue
Detroit, Michigan 48207

KANSAS CITY 1009 Cherry Street
Kansas City, Missouri 64106

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

MINNEAPOLIS 240 Hennepin Avenue
Minneapolis, Minnesota 55401

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

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

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

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

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

FDA BUREAU OF DRUG ABUSE CONTROL FIELD OFFICES

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

BALTIMORE 401 Water Street
Baltimore, Maryland 21202

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

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

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

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

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

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

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

state actions

New Officials in South Carolina

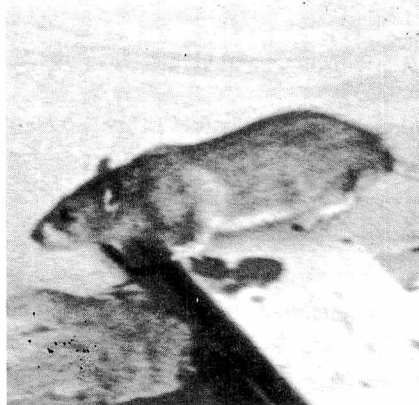
The new Deputy Commissioner for the South Carolina Department of Agriculture is Ralph M. Magoffin. Former Deputy Commissioner Carl H. Stender retired on January 1. Mr. Magoffin joined the Department in 1942. Truluck Kelley, Chief Chemist, was promoted to Director of the Laboratory to replace Mr. Magoffin.

Dead Swine Processed A two-train collision near Wamego, Kans., on December 21 killed about 200 head of swine, which were taken to a rendering plant at Enterprise, Kans., for processing under supervision of Kansas State Food and Drug officials.

Eggs Embargoed A joint inspection of stocks of frozen eggs by inspectors from the California Bureau of Foods and Drugs and Los Angeles District disclosed 547 30-pound cans of decomposed eggs. The eggs were placed under embargo by State Inspectors and then destroyed under State supervision.

Pork Diverted to Lard California State officials quarantined approximately 40,340 pounds of pork products recently. The meat had been shipped from an eastern plant via rail, but when the train was delayed by a strike the meat thawed. A Federal Inspector rejected the meat when it arrived at the California consignee's plant. The lot was then sold to a local salvage dealer, but examination of the meat showed that it was decomposed. The entire lot was diverted for use as lard after being quarantined.

Rats Eradicated Baltimore City Health Department's war on rats has moved into the field. Health



aides recruited chiefly from inner city residents are eradicating rats on a block-by-block basis. The program, conducted with Maryland State funds, calls for a four-step campaign: remove food for rats and debris providing shelter; exterminate rats; correct housing defects; and maintain improved conditions.

Meat Dealer Fined Following extensive surveillance, a meat dealer from Lansing, Mich., was convicted recently of maintaining gross insanitary conditions. An inspector from the Food Inspection Division of the Michigan Department of Agriculture noticed the suspicious dealer while making a routine sanitary inspection. The dealer was making scattered meat deliveries over a five-county area in a small panel truck. The Division instigated a regular surveillance and learned that the distributor did not have a comminuted meat license and was conducting a meatcutting operation in a farmhouse. Nighttime surveillance was continued until late October, when

two food inspectors accompanied by two State police officers checked the premises. They found gross insanitary conditions but no meat suspected to be from illegal slaughter. Questioning revealed that the meat source was satisfactory, although the dealer had repackaged hamburger without legally required labeling. The dealer was fined \$75, plus costs of \$26.20, and given a 30-day suspended sentence. He has reportedly stopped his operations until he can find approved facilities.

Salmonella Program Advances

Two more States have started joint programs to eliminate *Salmonella* contamination from animal byproducts (see February FDA PAPERS). Representatives of the Division of Veterinary Medicine, Colorado Department of Agriculture; Animal Health Division, USDA; and FDA met in Limon, Colo., in December to instigate action. In Idaho, USDA and the Idaho Department of Agriculture initiated a program of inspection and sample examinations to further voluntary compliance by industry. FDA is participating by training local inspectors.

Pharmacists Warned Cross-contamination of penicillin was investigated recently by the Indiana State Board of Health, Division of Food and Drugs. The investigation showed that the penicillin was contaminated in a retail pharmacy due to poor dispensing procedures involving a tablet counter. The Division and the Indiana Board of Pharmacy are making a joint effort to inform the State's retail pharmacists of this possible hazard.

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 65 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market were reported in December. These included 37 seizures of foods: 3 because of poisonous and deleterious substances, 26 because of contamination, and 8 because of economic violations. Other seizures included 3 of vitamins and dietary foods, 18 of drugs, 2 of medical devices (including 1 of prophylactics), and 5 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Poisonous and Deleterious Substances		
Eggs, frozen/Buffalo, N.Y. 12/28/67	Brasher Bros., Inc./Burbank, Calif. (P,S)	Contain poisonous Salmonella micro-organisms.
Flour, Blue Ribbon Rye/St. Louis, Mo. 12/5/67	Globe Milling Co./Watertown, Wis. (M,S)	Contains DDT, a food additive not in conformity with regulations.
Potatoes, raw, white/Los Angeles, Calif. 11/20/67	Crater Lake Potato Distributors/Stukel, Oreg. (S)	Contain poisonous mercury.
Contamination, Spoilage, Insanitary Handling		
Bean Curd Roll, Preserved Turnips, Anise Seed, Shark Fins, Patis Sauce/Los Angeles, Calif. 11/15/67	Kwong-On-Lung Importers/Los Angeles, Calif. (D)	Swelled cans; partly decomposed; inaccurate quantity statement; insufficient ingredient listing; insect- and rodent-infested storage.
Beer/Anaheim, Calif. 11/28/67	The Walter Brewing Co./Pueblo, Colo. (M,S)	Insect-contaminated manufacturing equipment.
Black Turtle Soup Beans/Miami, Fla. 12/7/67	Green Bros., Inc./Miami, Fla. (D)	Held under insanitary conditions; insect contaminated.
Breeder 1171/Boston, Mass. 9/25/67	Channel Fish Co./Boston, Mass. (D)	Rodent contaminated.
Chocolat Royale, chocolate drink/Lexington, Ky. 12/4/67 and 12/5/67 (2 actions)	Chocolat Royale, Ltd./Cincinnati, Ohio (M,S)	Insect contaminated; partly decomposed.
Cocoa beans/Philadelphia, Pa. 9/1/67 (3 lots) Brooklyn, N.Y. 9/13/67	Atlantic Terminal & Warehouse Co., Inc./ Philadelphia, Pa., and Continental Terminals, Inc./ Brooklyn, N.Y. (D)	Held under insanitary conditions.
Eggs, frozen/Baltimore, Md. 12/7/67	Consolidated Cold Storage Co./Baltimore, Md. (D)	Partly decomposed; appeared thawed and refrozen.
Flour, enriched/New Orleans, La. 11/29/67	George W. Groetsch Wholesale Grocer/New Orleans, La. (D)	Held under insanitary conditions; insect contaminated.
West Point, Ga. 12/15/67	West Point Wholesale Grocery/West Point, Ga. (D)	Held under insanitary conditions.
donut, and sugar, Danish mix/Franklin Park, Ill. 12/21/67	Joe Lowe Corp./Melrose Park, Ill. (M,S)	"
Olives, Cocktail Onions/Denver, Colo. 12/7/67	Superior Honey & Olive Co. of Colorado/Denver, Colo. (D)	" ; fly contaminated.
Peanuts, shelled, Poppyseed, Caraway, Sesame seed/Detroit, Mich. 12/13/67	Philip Olender & Co./Detroit, Mich. (D)	Rodent contaminated.
Perch fillets/Chicago, Ill. 11/20/67	J. Kozloff Fish Distributors, Inc./Detroit, Mich. (P)	Partly decomposed.
Popcorn/Dallas, Tex. 11/30/67	Matthews Candy Co./Dallas, Tex. (D)	Held under insanitary conditions.
Raisins/Pawtucket, R.I. 11/21/67	Albert Jenkins Co., Inc./Pawtucket, R.I. (D)	Moldy.
Rice, Texas Panta/Atlanta, Ga. 12/8/67	Raley Bros., Inc./Atlanta, Ga. (D)	Held under insanitary conditions.
Salmon, frozen/Bellingham, Wash. 11/13/67	Marine Foods Packing Co./Yakutat, Alaska (P,S)	Partly decomposed.
Shrimp, frozen, breaded/Chicago, Ill. 11/20 and 12/6/67	Morgan City Freezer & Cold Storage Co./ Morgan City, La. (P,S)	Prepared and packed under insanitary conditions.
Green Bay, Wis. 11/9/67	"	" ; E. coli, staphylococci.
Appleton, Wis. 11/9/67	"	"
stuffed/Los Angeles, Calif. 11/14/67	"	"
meat/Los Angeles, Calif. 11/30/67	Young's Market Co./Los Angeles, Calif. (D)	Held under insanitary conditions.
Wheat/Spokane, Wash. 12/11/67	Edinburg Farmers Elevator Co./Edinburg, N. Dak. (S)	Rodent contaminated.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Economic Violations		
Beer, Gablinger's, canned and bottled/Suffern, N.Y. 12/7/67	Rheingold Breweries, Inc./Orange, N.J. (M,S)	False and misleading claims to be of significant value for reducing and weight control.
Cheese, swiss/City of Commerce, Calif. 11/15/67	Cache Valley Dairy Association/Smithfield, Utah (M,S)	Imitation swiss cheese.
Jellies and Preserves/Waterloo, Iowa 12/19/67	Santa Claus Industries/Waterloo, Iowa (D)	Insufficient and inconspicuous labeling.
Lemonade, fresh/Phoenix, Ariz. 11/21/67	Foremost Foods Co./Phoenix, Ariz. (D)	"Vitamin C Enriched" label is false and misleading; no vitamin C added.
Nuts, mixed/Ferndale, Mich. 12/18/67	Kar Nut Products Co./Ferndale, Mich. (D)	Contain mainly peanuts, vignette shows large amounts of other nuts.
Peaches, canned/North Kansas City, Mo. 11/27/67	California Cannery & Growers #7/Stockton, Calif. (P,S)	Below standard of fill of container for canned peaches.
Raspberry Preserves, red and black/Tacoma, Wash. 11/14/67	Sunnyview Farms, Inc./Portland, Oreg. (M,S)	Not in conformity with definition and standard of identity; less fruit, sugar in part substituted.
Whiting, frozen, dressed/St. Louis, Mo., and Hazelwood, Mo. 12/5/67	Empire Fish Co./Gloucester, Mass. (P,S)	"Pan Ready," "Thoroughly Cleaned," "Ready to Cook and Serve" label statements false and misleading; fish only partly eviscerated.
Vitamins—Dietary Food		
Apeten Vitamin Drops/Coral Gables, Fla. 11/28/67	Biosante Distributors, Inc./Coral Gables, Fla. (D)	False and misleading claims to be effective in stimulation of appetite, weight gain, and deficiency of vitamin B complex.
MUS-L-ON and MUS-L-ON, JR. (Vanilla and Chocolate)/Denver, Colo. 11/29/67	Packed for The Mus-L-On Co./Hayward, Calif. (M,S unknown)	False and misleading claims as special dietary food.
DRUGS / Human Use		
Adhesive Bandages/Marion, Ind. 12/1/67	Duke Labs., Inc./So. Norwalk, Conn. (S)	Below USP quality standard.
Aknemed/Wilson, N.C. 12/21/67	The Aknell Corp./Birmingham, Ala. (S)	False and misleading claims to be effective treatment for acne; inadequate directions for use; new drug not approved for safety and efficacy.
Bariatric Special Formulas/Coral Gables, Fla. 11/20/67	Milan Pharmaceuticals, Inc./Morgantown, W.Va. (M,S)	New drugs not approved for safety and efficacy.
Coccide Tablets/Zachary, La. 12/5/67	Reid-Provident Labs., Inc./Atlanta, Ga. (M,S)	New drug not approved for safety and efficacy.
Cuticura Cutitone Acne Cream/Los Angeles, Calif. 8/29/67	Campana Corp. (Div. of Purex Corp.)/Batavia, Ill. (M,S)	
Digoxin Injection/Santurce, P.R. 12/4/67	Dianovin Pharmaceuticals, Inc./Santurce, P.R. (D)	Below USP strength; not in conformity with required labeling information.
Elixir Sherex/DeFuniak Springs, Fla. 10/5/67	National Pharmaceuticals, Inc./Baltimore, Md. (M,S)	Inadequate directions for use.
Ergonovine Maleate .2mg./Edison, N.J. 12/5/67	Bellevue Laboratories, Inc./College Point, N.Y. (M,S)	Below USP quality and purity standards; contains less than declared amount of ergonovine maleate.
Femicin Tablets/Denver, Colo. 12/28/67	Thayer Laboratories, Inc./Metuchen, N.J. (M,S)	Insufficient warning of kidney damage.
Hormone Plus Facial Oil/Salt Lake City, Utah 11/28/67	Ex-Cel-Cis Beauty Products Co./Salt Lake City, Utah (D)	Below labeled strength; fails to limit application to 2 mgs. of estrone per month.
Lanpar SP RX 2117 T-375 Sodium Lyothionine/Denver, Colo. 12/8/67	Lanpar Co./Dallas, Tex. (M,S)	Label fails to bear required disclosure information; not processed in accordance with good manufacturing practice.
Lipo-K Capsules/Muskogee, Okla. 12/13/67	Marcen Laboratories, Inc./New Rochelle, N.Y. (M,S)	New drug not approved for safety and efficacy.
Methyltestosterone/Monrovia, Calif. 12/6/67	Town Paulsen & Co./Monrovia, Calif. (D)	Fails to meet NF potency standard.
Pantothenyl Alcohol/San Gabriel, Calif. 10/26/67	Bioproducts Research Laboratories, Inc./Tempe, Ariz. (M,S)	Not in conformity with good manufacturing practice regulations; shipped without required labeling.
Prednisone Tablets/Chicago, Ill. 12/5/67	United Research Laboratories/Philadelphia, Pa. (S)	Below USP quality and strength.
Preparation No. B-2851/Warren, Pa. 11/3/67	Myers Laboratories, Inc./Warren, Pa. (D)	Lacks warning statement; adequate directions cannot be written.
Sanestro Tablets/Albuquerque, N. Mex. 12/11/67	Sandia Pharmaceuticals, Inc./Albuquerque, N. Mex. (D)	Below labeled strength.
Thyroid Granulation/Kankakee, Ill. 12/11/67	Richlyn Laboratories, Inc./Philadelphia, Pa. (S)	Moldy.
VETERINARY / Medicated Feed		
Kelp, dried/Midvale, Utah 11/22/67	Berl B. Cook, t/a Fabulous Feed & Soil/Midvale, Utah (D)	False and misleading claims to produce lower mortality, faster growth, and better breeding in all livestock, including poultry.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
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MEDICAL DEVICES

Air Gard Models 1, 2A, 3, and 4/Madison, Wis. 11/30/67	Jem Patents, Inc./Commack, N.Y. (S)	False and misleading claims to relieve smarting eyes, headache, depression, asthma, second-degree burns, cancer.
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Prophylactics

No brand name given/Bronx, N.Y. 11/15/67	Ci-dal Compana Industrial de Articulos De-Latex/Sante Fe Republica, Argentina (M,S)	Defective; holes.
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HAZARDOUS SUBSTANCES

Antiquing Kits/Greensboro, N.C. 11/28/67	Guardsman Chemical Coating, Inc./Grand Rapids, Mich. (M,S)	Lack consumer protection information required by the Fed. Hazardous Substances Act.
Engine Tune-Up, Trans-X Stop Leaks/Augusta, Ga. 11/24/67	Haynes Chemicals, Inc./Jacksonville, Fla. (M,S)	"
Gun Guard Gun & Reel Oil Spray/Miami, Fla. 12/6/67	Mitchell Chemical Co., Inc./Milford, Conn. (M,S)	"
Sneezing Powder/Boston, Mass. 11/30/67	Walter Fink/Bremen, West Germany (S)	Contains dianisidine, an irritant.
Steel Brite, Ease Furniture Polish/Houston, Tex. 11/27/67	Malter Supply Co., Inc./Gretna, La. (M,S)	Lack consumer protection information required by the Fed. Hazardous Substances Act.

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

NAME, PLACE & DATE	PRODUCT	CHARGES & DISPOSITION	NAME, PLACE & DATE	PRODUCT	CHARGES & DISPOSITION
Macon Drug Store Robertsdale, Ala. 10/24/67	15,000 units of controlled drugs.	Inadequate records.	Barre E. Drug Co., Inc., t/a National Pharma- ceutical Manufac- turing Co., Inc. Baltimore, Md. 11/7/67	6,000,000 units of controlled drugs.	Inadequate records.
Samuel P. Myers, M.D. Los Angeles, Calif. 10/27 and 11/7/67	12,000,000 units of controlled drugs.	Inadequate records.	Dr. Louis J. Glass Baltimore, Md. 11/30/67	250,000 units of controlled drugs.	Inadequate records.
Denver Drug Co. Denver, Colo. 10/31/67	77,000 units of controlled drugs.	Inadequate records.	A. B. Littman, M.D. Minneapolis, Minn. 11/6/67	70,000 units of controlled drugs.	Inadequate records.
Hahn Pharmacy Denver, Colo. 11/27/67	15,000 units of controlled drugs.	Inadequate records.	Edward A. Devins, D.O. Kansas City, Mo. 10/16/67	3,110,000 units of controlled drugs.	Inadequate records.
Capital Heights Pharmacy Denver, Colo. 8/14/67	33,000 units of controlled drugs.	Inadequate records.	Fordview Drug Co., Phil Levine Kansas City, Mo. 12/11/67	20,000 units of controlled drugs.	Inadequate records.
Medical Discount, Inc. Miami, Fla. 10/30/67	435,000 units of controlled drugs.	Inadequate records.	Santa Fe Drug Co. Kansas City, Mo. 12/8/67	15,000 units of controlled drugs.	Inadequate records.
Wozniak Rexall Drug Store Chicago, Ill. 12/4/67	Undetermined quantities of depressant and stimulant drugs.	Inadequate records.	Lowell Michael Charnas and Fay Deborah Hoff Huntington, L.I., N.Y. 9/21/67	Laboratory equipment.	Failure to register; unlawful manufac- ture and possession of depressant and stimulant drugs.
Joseph H. Baker, M.D. La Crosse, Kans. 9/29/67	31,500 units of controlled drugs.	Inadequate records.	Broadway Pharmacy, Inc. Fargo, N. Dak. 12/5/67	33,000 units of controlled drugs.	Inadequate records.
Courtesy Pharmacy Metairie, La. 10/24/67	67,000 units of controlled drugs.	Inadequate records.			
Brumfields Baton Rouge, La. 11/2/67	100,000 units of controlled drugs.	Inadequate records.			

NAME, PLACE & DATE	PRODUCT	CHARGES & DISPOSITION
Kirkman Laboratories, Inc. Portland, Oreg. 12/7/67	4,500,000 units of controlled drugs.	Inadequate records.
Dumont Pharmacal Co. Philadelphia, Pa. 11/9/67	14,600,000 units of stimu- lant and depressant drugs.	Inadequate records.
Pace Pharmacal Co., Inc. Philadelphia, Pa. 10/4/67	5,000,000 units of amphen- amines, barbiturates, and combination drugs.	Inadequate records.
Timmerman & Blocker Drug Co. Edgefield, S.C. 11/15/67	37,505 units of controlled drugs.	Inadequate records.
Rays Pharmacy Henderson, Tex. 10/26/67	53,000 units of controlled drugs.	Inadequate records.
Dr. Joe Paul Alexander, D.O. Abilene, Tex. 11/27/67	106,000 units of controlled drugs.	Inadequate records.

NAME, PLACE & DATE	PRODUCT	CHARGES & DISPOSITION
Eulin B. Duvall, t/a Maple Avenue Pharmacy Dallas, Tex. 11/17/67	31,000 units of controlled drugs.	Inadequate records.
The Behren's Drug Co. Waco, Tex. 10/13/67	430,000 units of controlled drugs.	Inadequate records.
B & B Drug Store Robinson, Tex. 12/18/67	6,000 units of controlled drugs.	Inadequate records.
Richard Butterfield, t/a Fairway Pharmacy Salt Lake City, Utah 11/24/67	17,000 units of stimulant and depressant drugs.	Inadequate records and illegal sales.
Richard Butterfield, t/a Sixth Avenue Pharmacy Salt Lake City, Utah 11/23/67	17,000 units of stimulant and depressant drugs.	Inadequate records.

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

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

January 8, 1968: Fraud Order issued against **Fred Wilson**, Los Angeles, Calif. Solicitations of orders and sale through the mails of various products claimed effective for bringing possessor good luck.

January 9, 1968, Fraud Order against **Orle Products**, Los Angeles, Calif. Solicitations of orders and sale through the mails of perfume alleged to be aphrodisiacs named "DONFORMON" and "AMBREDISIAC."

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

December 22, 1967: **Norvig Products, Inc.**, Flushing, N.Y. Solicitation of orders and sale through the mails of a vitamin E preparation alleged to be of therapeutic value with respect to sexual ability and prowess.

January 5, 1968: **Human Factors**, Chico, Calif. Solicitations of orders and sale through the mails of instructions to public allegedly enabling purchaser to hypnotize others while they sleep.

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

December 21, 1967, **William E. Sheehan, Joseph A. Sheehan, Robert Lee Sheehan**, and **LeRoy J. Westberg** were indicted by Federal grand jury,

Des Moines, Iowa, charged with 20 counts of mail fraud. Scheme involved sale of hearing aids in the Des Moines area over a 7-year period.

notices of judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

- Alfalfa seed screenings**, at Vancouver, W. Dist. Wash.
Charged 3-3-67: when shipped by Nevada Alfalfa Seed Co., Oroville, Nev., the article contained a quantity of the added pesticide chemical toxaphene for which there was no tolerance or exemption; 402(a)(2)(B), 408(a). Default decree ordered destruction. (1)
- Brazil nuts, unshelled**, at Los Angeles, C. Dist. Calif.
Charged 12-29-66: while held for sale, the article contained the added poisonous and deleterious substance aflatoxin; 402(a)(1). Consent decree authorized release to Los Angeles Nut House, Los Angeles, Calif., for salvaging. (2)
- Cabbage, fresh**, at Winston-Salem, M. Dist. N.C.
Charged 9-22-66: when shipped by Carlos Combs, Woodlawn, Va., the article contained a quantity of the pesticide chemical toxaphene in excess of the tolerance; 402(a)(2)(B). Consent decree ordered destruction. (3)
- Celery, fresh, Lake Shore**, at Asheville, W. Dist. N.C.
Charged 5-31-67: when shipped by the Great Atlantic & Pacific Tea Co., Pompano Beach, Fla., the article contained the pesticide chemical parathion in excess of the established tolerance; 402(a)(2)(B), 408(a). Consent decree ordered destruction. (4)
- Celery, fresh, Miles Ahead**, at Waukesha, E. Dist. Wis.
Charged 9-23-66: when shipped by Watsonville, Calif., the article contained the pesticide chemicals parathion and methyl parathion in excess of the tolerance; 402(a)(2)(B). Default decree ordered destruction. (5)
- Corn, shelled**, at Greenville, E. Dist. N.C.
Charged 6-2-67: when shipped by Queen City Grain Co., Cincinnati, Ohio, the article contained the pesticide chemical captan for which there was no tolerance or exemption; and shelled corn treated with captan had been substituted in part for the article; 402(a)(2)(B), 408(a), 402(b)(2). Consent decree authorized release to shipper for salvaging. (6)
- Egg product, dried**, at Chicago, N. Dist. Ill.
Charged 9-26-66: when shipped by Monark Egg Corp., Kansas City, Mo., the article contained an added poisonous and deleterious substance, *Salmonella* micro-organisms; 402(a)(1). Consent decree authorized release to shipper for reconditioning. (7)
- Egg white solids**, at Lodi, E. Dist. Calif.
Charged 8-5-66: when shipped by Monark Egg Corp., Kansas City, Mo., the article contained an added poisonous and deleterious substance, *Salmonella* micro-organisms; 402(a)(1). Consent decree authorized release to shipper for reconditioning. (8)
- Yeast, dried, Torula**, at Chicago, N. Dist. Ill.
Charged 8-12-66: when shipped by Lake States Div., St. Regis Paper Co., Rhinelander, Wis., the article contained an added poisonous and deleterious substance, *Salmonella* micro-organisms; 402(a)(1). Default decree ordered destruction. (9)

FOOD / Contamination, Spoilage, Insanitary Handling

- Allspice and sage**, at Dallas, N. Dist. Tex.
Charged 6-23-67: while held by HLH Products, Dallas, Tex., the articles contained insects, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (10)
- Apples, diced, dehydrated**, at Dunkirk, W. Dist. N.Y.
Charged 2-13-67: while held for sale, the article contained moldy apples; 402(a)(3). Consent decree authorized release to Valley Evaporating Co., Yakima, Wash., for salvaging. (11)
- Beans, baby lima**, at Mineola, E. Dist. Tex.
Charged 6-7-67: when shipped by California Bean Growers Association, Oxnard, Calif., the article contained rodent filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Benham & Co., Inc., Mineola, Tex., for salvaging. (12)
- Biscuit mix**, at Los Angeles, C. Dist. Calif.
Charged 5-26-67: when shipped by Morrison Milling Co., Denton, Tex., the article contained rodent filth, and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (13)
- Blueberry sirup**, at Marshfield, W. Dist. Wis.
Charged 12-20-66: while held for sale, the article contained moldy, decomposed sirup; 402(a)(3). Default decree ordered destruction. (14)
- Brazil nuts, Holiday**, at Norridge, N. Dist. Ill.
Charged 2-27-67: when shipped by Robert L. Berner Co., from Chicago, Ill., to Cincinnati, Ohio, and returned to shipper, the article contained insect filth, and rancid and moldy nuts; 402(a)(3). Consent decree authorized release to shipper for reconditioning. (15)
- Chocolate liquor**, at Charlotte, W. Dist. N.C.
Charged 7-7-67: while held by Murray Chocolate Co., Inc., Charlotte, N.C., the article contained insect filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (16)
- Cocoa beans**, at Stockton, E. Dist. Calif.
Charged 5-1-67: while held by Port of Stockton, Stockton Port District, Cotton Compress Warehouse, Stockton, Calif., the article had been held under insanitary conditions; 402(a)(4). Consent decree authorized release to Holco Trading Co., Inc., New York, N.Y., for salvaging. (17)
- Cornbread mix**, at Milwaukee, Dist. Oreg.
Charged on or about 6-9-67: when shipped by the Morrison Milling Co., Denton, Tex., the article, labeled in part "Morrison's Corn Kits. Prepared corn bread mix 10c," contained rodent filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (18)
- Eggs, frozen**, at Brooklyn, E. Dist. N.Y.
Charged 6-27-67: when shipped by Producers Foods, Inc., New York, N.Y., from Newark, N.J., and Jersey City, N.J., the article contained decomposed eggs; 402(a)(3). Default decree ordered destruction. (19)
- Eggs, frozen**, at Buffalo, W. Dist. N.Y.
Charged 7-19-66: while held for sale, the article contained decomposed eggs; 402(a)(3). Consent decree authorized release to Edward C. Fallon, Inc., Buffalo, N.Y., for salvaging. (20)
- Eggs, frozen**, at Detroit, E. Dist. Mich.
Charged 8-2-66: when shipped by Weinberg Bros., Chicago, Ill., the article, labeled in part "Eggs . . . Packed by C. Kaitis Egg Co. . . . Chicago, Ill.," contained decomposed eggs; 402(a)(3). Consent decree authorized release to shipper for salvaging. (21)
- Eggs, frozen**, at Newark, Dist. N.J.
Charged 6-1-67: when shipped by the Manhattan Egg Co., Inc., New York, N.Y., the article contained decomposed eggs; 402(a)(3). Default decree ordered destruction. (22)
- Fish steaks, breaded, South African whiting, Randy's**, at Manassas, E. Dist. Va.
Charged 5-16-67: when shipped by Phillips Sea Food Kitchens, Inc., Exeter, Pa., the article contained excessive coliforms and a high total bacterial count, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (23)
- Flounder fillets, frozen**, at Hattiesburg, S. Dist. Miss.
Charged 5-12-67: while held for sale, the article contained decomposed fish fillets; 402(a)(3). Default decree ordered destruction. (24)
- Flour**, at Bridgeview, N. Dist. Ill.
Charged 12-14-67: when shipped by International Milling Co., New Prague, Minn., the article contained moldy flour; 402(a)(3). Consent decree authorized release to shipper for salvaging. (25)
- Flour**, at Carthage, E. Dist. Tex.
Charged 4-10-67: while held by Magnolia Grocery Co., Carthage, Tex., the article contained insect and rodent filth, and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (26)
- Flour**, at Texarkana, E. Dist. Tex.
Charged 5-24-67: while held by Joplin Eason Grocery Co., Tyler, Tex., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (27)
- Flour**, at Tupelo, N. Dist. Miss.
Charged 2-8-67: while held by J. J. Rogers & Sons, Tupelo, Miss., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (28)
- Malt**, at San Juan, Dist. P.R.
Charged 4-26-67: while held by Almacenes Maritimos, Inc., San Juan, P.R., the article contained rodent and insect filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (29)
- Mushrooms, chips, canned, Superior**, at Cincinnati, S. Dist. Ohio.
Charged 7-13-66: when shipped by Di Cecco, Inc., Avondale, Pa., the labeling lacked the name of the form of the mushroom ingredient present in the article as specified by the identity standard, and while held for sale, the article was, in part, decomposed; 403(2), 402(a)(3). Default decree ordered destruction. (30)
- Orange drink**, at Brooklyn, E. Dist. N.Y.
Charged 5-25-67: while held for sale, the article contained a decomposed substance and had an offensive metallic taste; 402(a)(3). Default decree ordered destruction. (31)
- Paprika, sesame seeds, and lupini beans**, at Detroit, E. Dist. Mich.
Charged 8-2-66: while held by Bommaritio Bros., Detroit, Mich., the paprika and sesame seeds contained insects, and all articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (32)
- Peaches, canned, Del Monte**, at Clearfield, Dist. Utah.
Charged 1-20-67: when shipped by California Packing Corp., Sacramento, Calif., the article contained mold and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree authorized donation to public/charitable institution for use as animal feed. (33)
- Peanuts, roasted, and cornmeal**, at New Orleans, E. Dist. La.
Charged 5-1-67: while held by the Great Atlantic & Pacific Tea Co., New Orleans, La., the peanuts contained rodent filth, and both articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (34)
- Peanuts, shelled**, at Minneapolis, Dist. Minn.
Charged 3-27-67: while held for sale, the article contained rodent filth; 402(a)(3). Consent decree authorized release to Hancock Peanut Co., Courtland, Va., for salvaging. (35)
- Peas, dried**, at Alma, W. Dist. Ark.
Charged 5-23-67: while held by HLH Products, Alma, Ark., the article contained rodent filth, and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (36)
- Pecan chips**, at Lawton, W. Dist. Okla.
Charged 3-2-67: when shipped by Azar Bros., Inc., El Paso, Tex., the article contained *E. coli*, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree authorized donation to public/charitable institution for use as animal feed. (37)
- Pecan chips, McCormick's**, at Omaha, Dist. Nebr.
Charged 3-21-67: when shipped by Azar Bros., Inc., El Paso, Tex., the article contained *E. coli* and bacterial filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (38)
- Pecan pieces**, at Milwaukee, E. Dist. Wis.
Charged 2-15-67: when shipped by Wynnewood Pecan Co., Wynnewood, Okla., the article contained *E. coli*, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for reconditioning. (39)
- Pecan pieces, Fleischmann**, at Atlanta, N. Dist. Ga.
Charged 4-19-67: when shipped by Standard Brands, Inc., San Antonio, Tex., the article contained *E. coli*, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Standard Brands, Inc., New York, N.Y., for salvaging. (40)
- Pecans, shelled**, at Anaheim, C. Dist. Calif.
Charged 3-27-67: when shipped by Louisiana Pecan Shelling Co., Mansfield, La., the article contained *E. coli*, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for salvaging. (41)
- Popcorn**, at Dallas, N. Dist. Tex.
Charged 6-6-67: while held by Edwards Warehouse, Inc., Dallas, Tex., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Parker Popcorn Co., Murray, Ky., for salvaging. (42)
- Poppyseed**, at Boston, Dist. Mass.
Charged 6-23-67: while held by Sparrow & Meins Chocolate Co., Inc., Boston, Mass., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (43)

Poppyseed, at Los Angeles, C. Dist. Calif.
 Charged 12-9-66: while held by Morton Reconditioning Co., Los Angeles, Calif., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (44)

Potatoes, at Alexandria, W. Dist. La.
 Charged 2-10-67: while held by Noah's Potato Chip Co., Alexandria, La., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (45)

Rice, Perfection, at Stuttgart, E. Dist. Ark.
 Charged 7-21-66: when shipped by Arkansas Rice Growers Cooperating Association, Stuttgart, Ark., to Chino, Calif., and thereafter returned, the article contained insect filth; 402(a)(3). Consent decree authorized release to shipper for salvaging. (46)

Sesame seed, at Los Angeles, C. Dist. Calif.
 Charged 3-13-67: while held by American Transportation Co., Los Angeles, Calif., the article contained insect filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Richard J. Spitz & Co., Inc., New York, N.Y., for salvaging. (47)

Shortening, at Kansas City, Dist. Kans.
 Charged 3-7-67: while held by Crissey Co., Kansas City, Kans., 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. (48)

Shrimp, breaded, frozen, at Kansas City, Dist. Kans.
 Charged 5-23-67: when shipped by Golden Shore Seafoods, Inc., Brunswick, Ga., the article contained *E. coli*, coagulase positive staphylococci, and bacterial filth; and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (49)

Shrimp, breaded, frozen, Singleton, at Landover, Dist. Md.
 Charged 11-28-66: when shipped by Singleton Packing Corp., Tampa, Fla., the article contained *E. coli*, coagulase positive staphylococci, and bacterial filth; and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for salvaging. (50)

Shrimp, frozen, at Los Angeles, C. Dist. Calif.
 Charged 3-27-67: when shipped from Japan, the article, labeled in part "Eastern Brand . . . Shrimp . . . Packed by Eastern Products Co., Ltd., Tokyo, Japan," contained bacterial filth and coagulase positive staphylococci; 402(a)(3). Consent decree authorized release to Trans-Pacific Distributors, Inc., Los Angeles, Calif., for export to the original foreign supplier. (51)

Soybeans, at Los Angeles, C. Dist. Calif.
 Charged 6-5-67: while held by Yamauchi Enterprises, t/a Matsuda & Hinode Tofu Co., Los Angeles, Calif., 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. (52)

Strawberries, sliced, frozen, at Buffalo, W. Dist. N.Y.
 Charged 3-1-67: when shipped by Kelley Farquhar & Co., Puyallup, Wash., the article, labeled in part "Staff Sliced Strawberries with Sugar Frozen Fresh . . . Distributed by Staff Supermarket Associates, Inc., Great Neck, N.Y.," contained decomposed strawberries; 402(a)(3). Default decree ordered destruction. (53)

Strawberries, sliced, frozen, at Maumee, N. Dist. Ohio.
 Charged 2-3-67: when shipped by Southland Frozen Foods, Inc., New York, N.Y., the article, labeled in part "Staff Sliced Strawberries with Sugar Frozen . . . Distributed by Staff Supermarket Associates, Inc., Great Neck, N.Y.," contained decomposed strawberries; 402(a)(3). Default decree ordered destruction. (54)

Tomatoes, canned, at Burlington, Dist. Vt.
 Charged 4-25-67: when shipped by Dade Farms, Inc., Princeton, Fla., the article, labeled in part "Good Hope . . . Tomatoes Distributed by Meridian Distributors New York 8-Chicago," contained fly eggs; 402(a)(3). Default decree ordered destruction. (55)

Tomatoes, canned, at Indianapolis, S. Dist. Ind.
 Charged 6-21-67: when shipped by Carolina Products Co., Inc., Inman, S.C., the article, labeled in part "Cedar Rock Brand Tomatoes . . . Distributed by Jones Bros. Canning Co., Greer S.C.," contained fly eggs and maggots; 402(a)(3). Default decree ordered destruction. (56)

Wheat, at Spokane, E. Dist. Wash.
 Charged 6-16-67: when shipped by Beach Coop. Grain Co., Beach, N. Dak., the article contained rodent filth; 402(a)(3). Consent decree authorized release to shipper for salvaging. (57)

FOOD / Economic and Labeling Violations

Beans, baby lima, Jack Rabbit, at Gering, Dist. Nebr.
 Charged 3-28-67: while held by Chester B. Brown Co., Gering, Nebr., which packed the article from bulk, the article's labeling contained false and misleading weight control claims and lacked the name and place of business of the manufacturer, packer, or distributor, and the required special dietary use information; 403(a), 403(e)(1), 403(j). Default decree authorized donation to public/charitable institution. (58)

Beans, green, canned, Perry Lou, at Oklahoma City, W. Dist. Okla.
 Charged 5-12-67: while held for sale, after being labeled by Stilwell Canning Co., Stilwell, Okla., the article fell below the standard of quality because of excess unstemmed units, and excess units shorter than one-half inch; 403(h)(1). Default decree authorized donation to public/charitable institution. (59)

Candy, jellies, at Lynn, Dist. Mass.
 Charged 4-26-67: while held for sale, the article was short weight (approx. 3.83 percent); 403(e)(2). Default decree authorized donation to public/charitable institution. (60)

Cheese, assorted, at Los Angeles, C. Dist. Calif.
 Charged 4-28-67: when shipped by Plymouth Cheese Counter, Plymouth, Wis., the article's label reading in part "Mission Pak Los Angeles Gifts of Sunshine from California . . . Mission Pak Company . . . Los Angeles" lacked a quantity of contents statement; 403(e)(2). Consent decree authorized release to Mission Pak Co., Los Angeles, Calif., for salvaging. (61)

Cheese, cheddar, at Denver, Dist. Colo.
 Charged 10-11-66: when shipped by Bert F. Allen, Hastings, Nebr., the label statement "Pasteurized" was false and misleading, and the article lacked conformity to the standard of identity, since it was not pasteurized or cured as required; 403(a), 403(g)(1). Consent decree authorized release to Continental Cheese, Inc., Red Cloud, Nebr., for reconditioning and relabeling. (62)

Cheese, provolone, at Los Angeles, C. Dist. Calif.
 Charged 4-19-67: when shipped by Le Prino Cheese Co., Denver, Colo., the valuable constituent milk fat had been omitted in part; the article fell below the standard of identity because its solids contained less than 45 percent milk fat; and the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, a quantity of contents statement, and the common or usual name of the article; 402(b)(1), 403(g)(1), 403(e)(1) & (2), 403(i)(1). Consent decree authorized release to shipper for salvaging. (63)

Chili pepper, King, at Phoenix, Dist. Ariz.
 Charged 2-17-67: while held by B. Peralta, Phoenix, Ariz., who had packed it, the

article was short weight (approx. 5 percent); 403(e)(2). Default decree authorized donation to public/charitable institution. (64)

Clams, stuffed, frozen, Matlaw's, at Milton, Dist. Mass.
 Charged 5-31-67: when shipped by Matlaw's Food Products, Inc., New Haven, Conn., the article was short weight (approx. 3.68 percent); 403(e)(2). Consent decree authorized release to shipper for reconditioning. (65)

Coffee, Espresso, canned, Caffé Vivo, at Los Angeles, S. Dist. Calif.
 Charged 7-11-66: when shipped by Eppens, Smith Co., Secaucus, N.J., the article was short weight (approx. 2 percent); 403(e)(2). Consent decree authorized release to shipper for salvaging. (66)

Crab, deviled, frozen, Sail, 2 seizure actions at Baton Rouge and Shreveport, La.
 Charged 10-24-66 and 11-22-66: when shipped by Bayou Foods, Inc., Mobile, Ala., the article contained codfish which had been substituted for deviled crab; the name deviled crab was false and misleading; and the label failed to bear the name of each ingredient; 402(b)(2), 403(a), 403(i)(2). Default decrees ordered destruction. (67)

Date pecan roll, canned, at Indianapolis, S. Dist. Ind.
 Charged 1-25-67: when shipped by Shamrock Cake Co., Grand Prairie, Tex., the article labeled in part "Sexton Date Pecan Roll . . . Distributed by John Sexton & Co. . . . Chicago, Ill.," was short weight (approx. 10.6 percent); 403(e)(2). Consent decree authorized release to the distributor for relabeling. (68)

Dressing, Brockles avocado, at Oklahoma City, W. Dist. Okla.
 Charged 9-27-66: when shipped by Brockles Foods Co., Dallas, Tex., green color had been added so as to make it appear better or of greater value and the labeling was false and misleading, since the article contained only a small amount of avocado ingredient and the avocado flavor could not be detected; 402(b)(4), 403(a). Default decree authorized donation to public/charitable institution. (69)

Fruit drinks, at Berea, E. Dist. Ky.
 Charged 5-17-67: when shipped by M. Steffen & Co., Inc., Coloma, Mich., the articles' valuable constituent vitamin C was in part omitted (approx. 32 percent in pineapple-grapefruit drink, 56 percent in fruit punch, and 40 percent in orange drink); 402(b)(1). Default decree authorized donation to public/charitable institution. (70)

Jellies, mint, red currant, and red raspberry and currant, at Cleveland, N. Dist. Ohio.
 Charged 12-12-66: when shipped by Utt Juice Co., Tustin, Calif., the articles labeled in part "Bradens Treasures . . . Bradens California Products Inc., Distributors, Cleveland, Ohio," were short weight (approx. 3.38 to 3.75 percent); 403(e)(2). Consent decree authorized release to Bradens California Products for relabeling. (71)

Lobster sauce, canned, at Jersey City, Dist. N.J.
 Charged 8-23-66: when shipped by Duxsee Div. of Fred Fear & Co., Lewes, Del., the article labeled in part "Progresso Brand Lobster Sauce . . . Distributed by Uddo & Taormina Corp." was labeled false and misleading since the article contained insufficient lobster meat to characterize it; 403(a). Default decree authorized donation to public/charitable institution. (72)

Milk, nonfat, dry, at St. Joseph, W. Dist. Mo.
 Charged 5-18-66: when shipped by J. M. Swank Co., Iowa City, Iowa, the article labeled in part "Nonfat Dry Milk Solids Spray Process . . . Spooner Coop . . . Spooner, Wis." contained another substance which had been substituted for nonfat dry milk, and the label statement "Nonfat Dry Milk" was false and misleading; 402(b)(2), 403(a). Default decree ordered destruction. (73)

Oleomargarine, Holland Maid, at Vestal, N. Dist. N.Y.
 Charged 11-17-66: after shipment by Old Dutch Foods, Inc., Blasdell, N.Y., and while held for further sale in the same State in which produced, the article lacked conformity to the standard of identity, since it contained less than 80 percent fat; 403(g)(1). Consent decree ordered destruction. (74)

Oleomargarine, Old Dutch, Shiremanstown, M. Dist. Pa.
 Charged 11-3-66: when shipped by Old Dutch Foods, Inc., Blasdell, N.Y., the article lacked conformity to standard of identity, since it contained less than 80 percent fat; 403(g)(1). Default decree ordered destruction. (75)

Peaches, canned, halves, Inman, at Church Point, W. Dist. La.
 Charged 1-27-67: when shipped by Carolina Products Co., Inc., Inman, S.C., the article fell below standard of quality because of excessive variation in size; 403(h)(1). Default decree authorized donation to public/charitable institution. (76)

Peas, Tidewater Fancy, at Charleston Heights, Dist. S.C.
 Charged 4-17-67 and 5-3-67: when shipped by Kent Canning Co., Gibson, Ga., the article's label vignette depicting field peas and snap beans and the name "Field Peas With Snaps" were false and misleading, since the article did not contain the proportion of snap beans depicted nor sufficient snap beans to characterize the article; 403(a). Consent decree authorized release to shipper for reconditioning. (77)

Perch fillets, frozen, at Chicago, N. Dist. Ill.
 Charged 8-15-66: when shipped by Bornstein Sea Foods, Inc., Bellingham, Wash., the article labeled in part "Frozen Ocean Fresh . . . Icelandic Ocean Perch Fillets . . . Packed by Coldwater Seafood Corp., Scarsdale, N.Y." contained Pacific Ocean perch (*Sebastes alutus*) which had been substituted for Atlantic Ocean perch (*Sebastes marinus*) from Iceland, and the labeling was false and misleading with respect to the nature and origin of the article and its being packed by Coldwater Seafood Corp., Scarsdale, N.Y.; 402(b)(2), 403(a). Consent decree authorized release to Coldwater Seafood Corp., for relabeling. (78)

Shrimp, canned, Sea Trader, at Phoenix, Dist. Ariz.
 Charged 12-7-66: when shipped by Safeway Stores, East Stockton, Calif., broken pieces of shrimp had been substituted for whole shrimp, and the label's description of the article was false and misleading; 402(b)(2), 403(a). Default decree authorized donation to public/charitable institution. (79)

Sorghum sirup, at Knoxville, E. Dist. Tenn.
 Charged 4-5-67: when shipped by St. Clair Foods Co., Princeton, W. Va., cane and corn sirups had been substituted for sorghum sirup; cane and corn sirups had been added, mixed, and packed with the article to reduce its quality and to make it appear better and of greater value than it was; the label was false and misleading as to content, and lacked the common or usual name of each ingredient; 402(b)(2), 402(b)(4), 403(a), 403(i)(2). Default decree authorized donation to public/charitable institution. (80)

Soy sauce packets, at Pittsburgh, W. Dist. Pa.
 Charged 4-24-67: when shipped by Delicious Food Products Co., Chicago, Ill., the packets of the article lacked a label bearing the name and place of business of the manufacturer, packer, or distributor, and the common or usual name of the article and its ingredients; 403(e)(1), 403(i)(1) & (2). Default decree authorized donation to private/charitable institution. (81)

Tea in bags, at Boston, Dist. Mass.
 Charged 6-15-67: while held by New England Tea Packing Co., Inc., Boston, Mass., which blended and repacked the article from bulk, the article labeled in part "Orange Pekoe and Pekoe 100 Tea Bags Packed for Stop & Shop Boston, Mass.," "Arbutus . . . Tea Bags . . . Packed for Franklin Distributors Boston, Mass.," and "Tea Bags . . . LaTouraine Coffee Co., Inc., Boston, Mass." was short weight (Stop & Shop Tea, approx. 2 percent; Arbutus Tea, approx. 2.13 percent; LaTouraine Tea, approx. 2.2 percent); 403(e)(2). Consent decree authorized release to dealer for reconditioning. (82)

Tomatoes, canned, Ro-Tel, at Oklahoma City, W. Dist. Okla.
 Charged 7-7-67: when shipped by Elsa Canning Co., Elsa, Tex., the article fell below

standard of quality because of excess peel; 403(h)(1). Default decree authorized donation to public/charitable institution. (83)

Tunafish, canned, at Los Angeles, C. Dist. Calif.

Charged 3-2-67: when shipped by Nichimen Co., Ltd., Tokyo, Japan, the article fell below the standard of fill since the weight of the pressed cakes of the solid pack tuna was less than that prescribed; 403(h)(2). Consent decree authorized release to Shimmitzu Shokuhin Kaisha, Ltd., for salvaging. (84)

Tunafish, canned, Star-Kist, at New York, S. Dist. N.Y.

Charged 9-13-66: when shipped by Star-Kist Caribe, Inc., Mayaguez, P.R., and Star-Kist Foods, Inc., Terminal Island, Calif., the article fell below standard of fill since the average weight of pressed cakes of the solid pack tuna was less than that prescribed; 403(h)(2). Consent decree authorized release to Star-Kist Foods, Inc., for salvaging. (85)

FOOD AND COLORING ADDITIVES

Cheese, grated, Parmesan and Romano, at Los Angeles, C. Dist. Calif.

Charged 1-3-67: when shipped by Arthur Schuman, Inc., New York, N.Y., the article contained the nonconforming food additive benzene hexachloride (BHC); 402(a)(2)(C), 409. Default decree ordered destruction. (86)

Mix of rice crackers, peas, beans, and nuts, Queen Brand, at Los Angeles, C. Dist. Calif.

Charged 3-30-67: when shipped by Tokyo Mutual Trading Co., Ltd., Tokyo, Japan, and while held by Mutual Trading Co., Inc., Los Angeles, Calif., after repacking in part by such dealer, the article contained a nonconforming color additive; and the article's labeling failed to declare the presence of artificial coloring; 402(c), 706(a), 403(k). Default decree ordered destruction. (87)

Nutri-Kings food supplement tablets and Nutra-Life "100" geriatric tablets, at Glendale and Los Angeles, C. Dist. Calif.

Charged 7-21-66: when shipped by Universal Nutritions, Inc., New York, N.Y., the Nutri-Kings food supplement tablets contained the nonconforming food additives vitamin K, folic acid, menadione, cobalt, iodine, fluorine, and molybdenum; the Nutra-Life "100" geriatric tablets contained the nonconforming food additive iodine; and both articles contained false and misleading representations of nutritional value for certain ingredients such as alfalfa leaves concentrate, silicon, parsley, and pantothenic acid; 402(a)(2)(C), 403(a). Consent decree adjudged the articles adulterated while held for sale after shipment by reason of the presence of nonconforming food additives, and ordered the articles destroyed. (88)

Paracelsus mineral preparation, at Lakewood, N. Dist. Ohio.

Charged 5-5-67: while held by American Biochemical Co., Lakewood, Ohio, which had manufactured the article from ingredients shipped in interstate commerce, the article contained the nonconforming food additives lithium carbonate and potassium nitrate; 402(a)(2)(C), 409. Default decree ordered destruction. (89)

VITAMINS / DIETARY FOODS

Amo-Tabs tablets, Stress-O-Vite tablets, Appetone tablets, Bob Mathias Food tablets, Maxitron capsules, and other vitamin/dietary supplement tablets, at Akron, N. Dist. Ohio.

Charged 10-2-64: when shipped by General Nutrition Corp., Pittsburgh, Pa., the labeling of Amo-Tabs amino acid tablets contained false and misleading claims of special nutritional value as providing a significant amount of protein, when the article did not provide a significant amount of protein, 403(a); the labeling of the article labeled in part "Prevention Vitamins and Minerals . . . Distributed by Natural Sales Co. . . . Pittsburgh" contained the nonconforming food additive fluorine, and contained false and misleading claims: that older persons have a special vitamin-mineral requirement different from that of adults generally; that "Need in human nutrition has not been established" as applied to zinc; and that the nutritional value of the article was enhanced by a number of ingredients such as biotin, sodium, copper, lysine, alfalfa, and cabbage; 402(a)(2)(C), 403(a). The labeling of Stress-O-Vite vitamin tablets contained false and misleading claims for stress and strain caused by severe injury, infection, surgery, and fever, 403(a); the labeling of Appetone tablets contained false and misleading claims concerning lysine, protein, and niacin, when lysine was not of special nutritional importance and the article's quantities of protein and niacin were insignificant, 403(a); the labeling of Bob Mathias Protein Food tablets contained false and misleading claims concerning the article's nutritional value as providing protein and concerning its value in improving one's athletic capabilities and physical condition, 403(a); the labeling of Maxitron vitamin-mineral capsules contained false and misleading claims concerning the value of the article because of high potency and because of ingredients such as calcium, magnesium, choline, biotin, and lemon bioflavonoid complex, 403(a); and the labeling of the article labeled in part "Bob Mathias Natural Source Multi-Vitamins . . . Distributed only by Natural Sales Co. . . . Pittsburgh" contained false and misleading claims concerning the article's enhancement by ingredients such as biotin and choline, and concerning the article's value in improving one's athletic capability and physical condition; 403(a). Consent decree specifying findings of certain misbrandings ordered destruction. (90)

Dietary food supplement tablets, at Oxon Hill, Dist. Md.

Charged on or about 9-6-66: while held for sale, the valuable constituent vitamin C had been in part omitted or abstracted and the labeling was false and misleading since the article contained less of the declared ingredient; 402(b)(1), 403(a). Default decree ordered destruction. (91)

Soy sauce, at Los Angeles, S. Dist. Calif.

Charged 5-10-66: when shipped by Nishimoto Trading Co., Ltd., Kobe, Japan, the label of the article reading in part "Low Salt Shoyu Fujiboshi . . . Hiroshima Shoyu Co., Ltd., Hiroshima, Japan" contained false and misleading claims for use in the diet for treating hypertension, heart, kidney, and liver ailments; and its label lacked the common or usual name of each ingredient; and lacked required special dietary use information as to its sodium properties; 403(a), 403(i)(2), 402(j). Default decree ordered destruction. (92)

DRUGS / Human Use

Vitasafe dietary supplement capsules, at Middlesex, Dist. N.J.

Charged 10-10-60 and amended 4-5-61 and 9-10-62: when shipped and while held by Vitasafe Corp., Div. of Consolidated Sun Ray, Inc., Middlesex, N.J., the labeling contained false and misleading statements of nutritional fact, and false and misleading therapeutic claims; and the labeling lacked adequate directions for the articles' intended uses; 403(a), 502(b), 502(f)(1). Claimant, Vitasafe Corp., denied the charges and also contended that the 3,730,000 pieces of promotional literature in the Vitasafe warehouse were not at the time "labeling" within the meaning of the law. Subsequently, upon motion of the Government and the waiver of objections of the claimant, the charges were amended to specify not only Vitasafe Formulas "M" and "W," but also Vitasafe "CF" and "Queen Formula with Royal Jelly Supplement for Women." A further amendment charged that the articles were misbranded while held for sale after shipment in interstate commerce, as well as when introduced into and while in interstate commerce. After trial by the court, the articles were found to have been misbranded; and the articles and their labeling were condemned. 226 F. Supp. 226 (1964).

Charged 8-17-64 in a complaint for injunction against Vitasafe Corp., Nutritional Quality Control, Inc., The Dollar Vitamin Plan, Inc., Life Nutrition, Inc., International Oil & Metals Corp., Dr. Parker Medicine Co., Philip S. Volosov, manager of the Middlesex, N.J., plant and vice president of Dr. Parker Medicine Co., and Henry D. Cohen, secretary of Vitasafe Corp. and International Oil & Metals

Corp.: that the defendants were in the business of distributing Vitasafe capsules and similar products; that the corporations were interlocking corporations sharing a number of the same officers and directors; that the methods of operation included the packaging of such capsules, the advertising of them, in newspapers and periodicals, and by direct mail, and the mailing of capsules to buyers on the basis of contractual monthly delivery until cancelled; and that the capsules are misbranded as charged in the seizure action. The court issued a temporary restraining order and after a hearing issued a preliminary injunction enjoining the violations complained of. 235 F. Supp. 84 (1964).

On appeal, the circuit court affirmed the district court as to the condemnation of the seized articles, but reversed as to the condemnation of the promotional literature seized at the defendants' warehouse, which had actually never been employed as labeling. The circuit court found that the injunction was too broad and required that it be limited so as not to include sales which were the result of solicitation by proper post-decree literature, and limited so as to prohibit the use with the articles of literature which contained the specified violative statements and representations, but not of literature containing representations described only as "otherwise false and misleading." 345 F. 2d 864 (1965); cert. denied, 382 U.S. 918 (1965). (93)

Amphetamine phosphate tablets, at Los Angeles, C. Dist. Calif.

Charged 9-27-66: while held for sale, after manufacture by Leo Linden Labs., Culver City, Calif., from dextro-amphetamine phosphate shipped in interstate commerce, the article's strength differed from N.F. standards, and the article contained dextro-amphetamine phosphate which had been substituted for amphetamine phosphate; 501(b), 501(d)(2). Default decree ordered destruction. (94)

Aspryn pediatric syrup, at Aibonito, Dist. P.R.

Charged 9-19-66: while held by Town Pharmaceutical, Inc., Aibonito, P.R., after manufacture from ingredients shipped in interstate commerce, the article was overstrength (approx. 155 percent of declared chlorpheniramine maleate) and the name "Aspryn" was false and misleading, since the article contained no aspirin; 501(c), 502(a). Default decree ordered destruction. (95)

Boric acid solution, N.F., at Portland, Dist. Ore.

Charged 12-21-66: when shipped by Stanlans Warehouse, Gardena, Calif., the label lacked the name of the manufacturer, packer, or distributor, and the place of business of the distributors; the labeling lacked adequate directions for use as a douche and for cleansing minor wounds; and the labeling lacked adequate warning; and the label did not conform to N.F. standards since it lacked prescribed directions for use in the eyes; 502(b)(1), 502(f)(1), 502(f)(2), 502(g). Default decree ordered destruction. (96)

Ceetex vitamin C tablets, at Houston, S. Dist. Tex.

Charged 6-6-66: while held by Pure Pharmaceutical Co., Houston, Tex., the bottle label and the accompanying leaflets printed locally on order of the dealer contained false and misleading claims for such conditions as arthritis, back pains, and avoidance of surgery; 502(a). Consent decree authorized release to dealer for relabeling. (97)

Di-amphetamine sulfate tablets, at Erie, W. Dist. Pa.

Charged 9-27-66: while held for sale the di-amphetamine sulfate strength of the article was deficient; 501(c). Default decree ordered destruction. (98)

Elicon Young silicone injection, at Stuart, S. Dist. Iowa.

Charged 9-28-66: when shipped by Koken Kogyo Co., Ltd., (Japan Medical Plastics Center), Tokyo, Japan, the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (99)

Ethinyl estradiol tablets, U.S.P., at Glendale, C. Dist. Calif.

Charged 1-18-67: when shipped by Lanpar Co., Dallas, Tex., the ethinyl estradiol strength of the article was deficient; 501(b). Consent decree authorized release to shipper for salvaging. (100)

H-3 procaine hydrochloride injectable and troches, at Studio City, S. Dist. Calif.

Charged 4-22-66: when the injectable was shipped by Richlyn Laboratories, Inc., Philadelphia, Pa., it was a new drug without an effective approved New Drug Application—505(a); when the injectable was shipped as described above and while it was held by D&C Supplements, I/a B. Younger Co., Studio City, Calif., the labeling lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information—502(f)(1); and while the injectable and the troches were being held by the firm of D&C Supplements, their labeling contained false and misleading therapeutic claims for old-age conditions, Parkinson's disease, arthritis, and ulcers—502(a). Default decree ordered destruction. (101)

Halsion vitamin A combination capsules and tablets, 2 seizure actions at Denver, Dist. Colo., and Los Angeles, S. Dist. Calif.

Charged 5-27-63 and 3-21-64: when Halsion capsules were shipped by Allan Drug Corp., Los Angeles, Calif., and while Halsion tablets were held at Los Angeles, Calif., by Allan Drug Corp., and others, after shipment in interstate commerce, the labeling contained false and misleading claims about the articles' use for acne, pimples, and other skin disorders; 502(a). Allan Drug Corp. claimed the articles and moved to dismiss the Denver action, contending the issues had been previously adjudicated in an action before the Post Office Department. This motion was denied by the court at Denver, on the basis that the issues were different because proof of wrongful or fraudulent intent was a requirement in the Post Office case, but was not a requirement in this action. Thereafter the Los Angeles action against the tablets was transferred to Denver and consolidated for trial with the action against the capsules. After trial by the court, the articles were found to be misbranded, were condemned, and were authorized to be released to the claimant for relabeling. When the parties could not agree on new labeling, the court authorized new revised labeling which the court considered to be in compliance with the law. The Government appealed on the grounds that the revised labeling would continue to misbrand the articles and that the revised labeling would make the articles a new drug for which no New Drug Application had been approved.

Upon appeal, the circuit court said the trial court had a wide discretion in determining whether a condemned article may be delivered to a claimant to be brought into compliance, that the question whether a condemned article has been brought into compliance is a different matter, that the Secretary's powers undoubtedly include "broad authority to determine whether, and in what manner the labeling may be brought within compliance with the Act," and that, though the final decision lies with the courts, great weight must be given to the administrative decision. The circuit also said:

"We are concerned with a condemned article, condemned because of false and misleading labeling. In determining the ultimate question whether the condemned product shall be reintroduced into commerce, we look at the fundamental purpose of the [Drug] Amendments [of 1962] to tighten administrative control and close up loopholes to the end that the labeling on products affecting the public health and safety shall speak the truth in language that the unsuspicious purchaser can understand. * * *

"Judged in this context, we construe the critical language of the Grandfather Clauses to exempt drugs not generally recognized as effective if on the effective date of the Act the labeling contained the same representations concerning its use, and thus confine the exemptions to drugs intended solely for use under conditions prescribed on the effective date of the Act. Given this interpretation, the condemned article loses the immunity of the Grandfather Clause and becomes a new drug subject to § 355. * * *

"It is enough to say that where, as here, an article has been condemned as mislabeled in fact and misbranded in law, it can be brought into compliance and reintroduced for the same or similar use only as a new drug under the procedures prescribed in § 355.

"Judgment is reversed, and the case is remanded with directions to proceed accordingly." 357 F. 2d 713; cert. denied, 385 U.S. 899.

Thereafter, pursuant to stipulation, the articles were ordered destroyed. (102)

Head-Aids APC tablets, at Los Angeles, C. Dist. Calif.

Charged 8-17-66: while held by Wallich Labs., Los Angeles, Calif., after repacking, the labeling of the article lacked adequate warnings; 502(f)(2). Consent decree authorized release to Fred R. Wallich, t/a Golden State Supply Co., Los Angeles, Calif., for relabeling. (103)

Hypercin antacid tablets, at Chicago, N. Dist. Ill.

Charged 3-3-67: while held by Consolidated Royal Chemical Corp., Chicago, Ill., which packed and labeled the article, the labeling contained false and misleading claims for relief of ulcer symptoms, and its labeling lacked adequate directions for use for such purposes; 502(a), 502(f)(1). Consent decree authorized release to the dealer for relabeling. (104)

Jenasol royal jelly capsules, at Milton, W. Dist. Wash.

Charged 7-29-58 and 8-7-58: when shipped by Jenasol Co., New York, N.Y., and while held by O. E. Haugland, Milton, Wash., the labeling, some of which had been printed on order of the dealer, contained false and misleading claims, including claims for increasing sexual vitality and extending the span of life; 502(a). The article was claimed by Marion Schere, t/a Jenasol Co., after which the libel action was removed to the Dist. of N.J. The claimant declined to answer interrogatories on the grounds that the matters inquired into were privileged under the 5th Amendment of the U. S. Constitution and criminal liabilities might be imposed on the claimant for the same alleged wrong. The Government moved for an order compelling answers to its interrogatories, and also for a protective order on the ground that since the claimant had declined to answer the Government's interrogatories it was unjust to require the Government to answer the claimant's interrogatories. The court denied the motions. After trial, the court held that the drug was misbranded by false and misleading labeling (200 F. Supp. 1). The Government then moved to amend the libel to include a prayer for an injunction against interstate shipment of the drug. The court granted the motion and enjoined the Jenasol Co. against the interstate shipment of the drug with the labeling which had been found to be false and misleading. (201 F. Supp. 915.) The Court of Appeals affirmed the findings of misbranding, but reversed the decision as to injunctive relief on the basis that it was substantially prejudicial to allow a new and different prayer for relief after the trial and at the very end of the case (320 F. 2d 564). (105)

Lincoicin lincomycin capsules, at Cincinnati, S. Dist. Ohio.

Charged 10-27-66: when shipped by Upjohn Co., Kalamazoo, Mich., a medical journal advertisement for the article lacked fair balance in the brief summary relating effectiveness, because of omissions, in certain specified contexts, concerning sensitivity study requirements before use as sole antibiotic therapy, concerning adverse experiences of a few hypersensitivity reactions, and concerning hematologic toxicity, and the frequency of severe diarrhea; and the advertisement also lacked certain specified information concerning precautions as to duration of the treatment of B-hemolytic streptococcal infections, concerning the serious nature of side effects in cases of hypersensitivity reactions, and the agents which should be available for emergency treatment of side effects, concerning the precaution of sensitivity studies in certain therapy, and concerning the misleading change of the statement covered by antibiotic certification, "other adverse reactions observed in a small proportion of patients," into "side effects of small proportions" in the advertisement; 502(n). Consent decree authorized donation to public/charitable institution. (106)

MacKenzie Regulators tablets, at Seattle, W. Dist. Wash.

Charged on or about 9-27-66: while held by G. O. Guy Drugs, Seattle, Wash., after being in part repacked, the article's label lacked the name and place of business of the manufacturer, packer, or distributor; and the labeling lacked adequate warnings for preparations containing belladonna; 502(b)(1), 502(f)(2). Default decree ordered destruction. (107)

Meltabs aspirin tablets, U.S.P., at Buffalo, W. Dist. N.Y.

Charged 5-11-67: while held by Direct Laboratories, Inc., Buffalo, N.Y., the strength and quality of the article, manufactured by the dealer from aspirin shipped in interstate commerce, were deficient since the article was deficient in aspirin (approx. 8 percent) and the article failed the U.S.P. disintegration test; and the labeling which made sore throat claims, lacked adequate warnings against dangerous and unsafe uses concerning severe and persistent sore throat, and concerning duration of use; 501(b), 502(f)(2). Consent decree ordered destruction. (108)

Mineral oil, heavy, U.S.P., Arthur's and Truman's, at Atlanta, N. Dist. Ga.

Charged 8-22-66: while held by Cheatham Chemical Co., Atlanta, Ga., after repacking, the labeling lacked adequate directions for use and adequate warnings as a mineral oil laxative; 502(f)(1), 502(f)(2). Consent decree authorized release to Cheatham Chemical Co., Atlanta, Ga., for relabeling. (109)

Pancreas substance, lymphatic substance, heart substance, and suprarenal cortex substance, at Salt Lake City, Dist. Utah.

Charged 8-2-66: when shipped by Cudahy Laboratories, Div. of Cudahy Co., Omaha, Neb., the articles contained the added poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). Default decree ordered destruction. (110)

Pentracin facial cream, at Sayville, Long Island, E. Dist. N.Y.

Charged on or about 1-9-67: when shipped by Solo Labs, Inc., Chicago, Ill., and while held by Eileen Cortney, Inc., Sayville, Long Island, N.Y., the label and the dealer's labeling contained false and misleading therapeutic claims for skin troubles; 502(a). Default decree ordered destruction. (111)

Pepsin, N.F., at Philadelphia, E. Dist. Pa.

Charged 8-30-66: when shipped by Reheis Chemical Co., Div. of Armour Pharmaceutical Co., Kankakee, Ill., the article's purity and quality fell below N.F. standards by reason of containing *Salmonella*; 501(b). Default decree ordered destruction. (112)

Pyrrol capsules, OBCT capsules, Pabicitral tablets, and theodrine tablets, at Columbus, S. Dist. Ohio.

Charged 4-4-66: while held for sale, the labeling of all the articles lacked adequate directions and did not comply with the Rx drug exemption requirement for disclosure of information—502(f)(1); the Pabicitral tablets were approximately 92 percent deficient in hydrocortisone and their labels were false and misleading as to their content of such ingredient—501(c), 502(a); and the portion of the theodrine tablets which had been repacked by Haigis Food Products, Inc., Columbus, Ohio, had labels lacking (1) the name and address of the manufacturer, packer, or distributor, (2) the name and quantity or proportion of phenobarbital contained in the tablets and the habit-forming warning, (3) the name and quantity of each active ingredient, and (4) the required prescription legend; 502(b)(1), 502(d), 502(e)(1)(A)(ii), 503(b)(4). Default decree ordered destruction. (113)

Sinosan cold tablets, at Grand Rapids, W. Dist. Mich.

Charged 6-28-66: while held by The Chrisman Co., Grand Rapids, Mich., the labeling of the article which had been repacked in part by the dealer lacked adequate directions for use as to dosage, and adequate warnings against misuse; 502(f)(1), 502(f)(2). Consent decree authorized release to dealer for relabeling. (114)

Thyrorac T.D. tablets, at Glendale, C. Dist. Calif.

Charged 9-6-66: when shipped by Lanpar Co., Dallas, Tex., the circumstances of the article's manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice; and the thyroid strength of the article was deficient; 501(a)(2)(B), 501(c). Default decree ordered destruction. (115)

Una-Trim weight-control tablets, at Hollywood, S. Dist. Fla.

Charged 5-11-67: while held by Imperial Sales Co., Hollywood, Fla., which had packed and labeled the article, the article was deficient in quality, since when tested for disintegration, the article failed to release the active ingredient benzocaine; and the labeling contained false and misleading claims for weight control and appetite appeasement; 501(c), 502(a). Default decree ordered destruction. (116)

DRUGS/Veterinary

Sodium sulfamethazine injection, at Winchester, S. Dist. Ill.

Charged 9-20-66: when shipped by Vet Products Corp., Kansas City, Mo., the article was deficient in sodium sulfamethazine; the labeling was false and misleading, since the article was deficient in sodium sulfamethazine; and the labeling contained false and misleading therapeutic claims for diseases in animals; 501(c), 502(a). Default decree ordered destruction. (117)

Tetratin capsules, at Zachary, E. Dist. La.

Charged 9-1-66: while held by Gulf Coast Labs., Inc., t/a Diamond Labs. Sales Corp., Zachary, La., after repacking, the labeling lacked adequate directions for use and lacked adequate warnings as an anthelmintic for veterinary use; 502(f)(1), 502(f)(2). Default decree ordered destruction. (118)

MEDICAL DEVICES

Contrex electronic muscle stimulator, at Nashville, M. Dist. Tenn.

Charged 4-3-67: while held by Contrex of Tennessee, Nashville, Tenn., the accompanying booklet contained false and misleading therapeutic claims, and the labeling lacked adequate directions for use for the therapeutic uses for which the article was offered by Mr. Robert S. Dyson, dealer sales representative, and by local newspaper advertisements; 502(a), 502(f)(1). Default decree ordered destruction. (119)

Myofasciatron electric generator, at Pittsburgh, W. Dist. Pa.

Charged 3-11-66: when shipped by Electro-Therapeutic Co., Niles, Ill., the accompanying booklet and leaflets contained false and misleading therapeutic claims for such conditions as arthritis, ulcers, fungi infections, and poor circulation; and the article lacked adequate directions and did not comply with the Rx device exemption requirement for disclosure of information; 502(a), 502(f)(1). Default decree ordered destruction. (120)

Niagara pads, chairs, hand units, and other electric heat/vibrator units, at Los Angeles, S. Dist. Calif.

Charged 7-20-66 and amended 8-5-66 and 9-9-66: while held by Niagara Therapy Manufacturing Corp., Los Angeles, Calif., the labeling lacked adequate directions for use for arthritis, ulcers, heart trouble, diabetes, constipation, polio, and other conditions for which the articles were offered by Walt Edwards, dealer sales representative; 502(f)(1).

Niagara Therapy Manufacturing Corp., appearing specially, moved to dismiss on the ground that the U. S. Marshal had seized articles in addition to those described in the warrant issued to the marshal since they were of different model numbers and had been shipped on different dates. On 8-5-66, the Government filed an amended complaint, which was the same as its original pleading except that it itemized the articles actually seized and alleged that they had been shipped "on various dates prior to July 20, 1966". On 8-10-66, the court granted the dealer's motion saying:

"The present state of affairs is that virtually the entire stock in trade of Niagara has been seized and is threatened with condemnation because of a purported single oral sales 'pitch' by one salesman. There is no showing that the capabilities attributed to the device by the salesman are in any manner supported by promotional literature published or distributed by Niagara, nor is there any contention by the Government that Niagara in any manner encouraged, approved, or even knew of the claims that the salesman made concerning the devices, as related in the complaint. Insofar as we are informed by the Government's pleading, the salesman's remarks complained of may have stemmed from a flight of fancy of his own and were limited to the single occasion that the complaint describes.

"Can a single instance of misrepresentation of the type here concerned cause to be 'misbranded' and made subject to seizure all of the inventory of articles that Niagara received in interstate commerce and had on hand at the time of the misrepresentation, as well as all of the similar articles that Niagara might thereafter receive from time to time?"

"Under the above [21 U.S.C. Section 352(f)(1), 21 C.F.R. Section 1.106(a)(1) (1966)] mentioned law and regulations, drugs and devices have been held to be misbranded when their labeling failed to contain directions as to how they were to be used in order to bring about the benefits attributed to their powers by promotional literature. *Irons v. United States*, 244 F. 2d 34 (1st Cir. 1957). Similar results have stemmed from representations made in public lectures. *Nature Food Centres, Inc. v. United States*, 310 F. 2d 67 (1st Cir. 1962).

"However, in every case that has been found to be pertinent to the problem here concerned, the whole course of conduct involving written and oral representations has been of a magnitude far exceeding that alleged here. No case has been discovered, and none have been offered for this Court's consideration, that is even comparable to a situation in which statements orally made by a salesman in a private home on only one occasion are alleged to warrant seizure of the products that he was promoting."

By way of analogy, the court also discussed cases involving prosecutions for mail fraud, and cited *Whitehead v. United States*, 245 Fed. 358 (5th Cir. 1917). *Osborne v. United States*, 17 F. 2d 246 (9th Cir. 1927), *Beck v. United States*, 305 F. 2d 595 (10th Cir. 1962), *Beck v. United States*, 33 F. 2d 107 (8th Cir. 1929). The court concluded that the representations alleged did not cause the articles seized to be misbranded and ordered the return of the articles to Niagara, without prejudice to the right of the Government to renew its attachment whenever it could allege and establish that the representations of the salesman set forth in the complaint were part of a course of conduct instituted, participated in, or permitted by Niagara or its responsible management.

The Government moved for leave to file a second amended and supplemental complaint which alleged that the devices were misbranded when shipped and while held for sale; that the misbranding arose out of a continuous course of sales promotional conduct which was participated in and permitted by Niagara Therapy Manufacturing Corp., and its responsible management; and that Mrs. Diana Watt (formerly Miss Diana Deinel), Mr. C. H. Minnick, Mrs. Annabelle Unger, Mrs. Eleanor Olis, Mr. Jack Watt, Mrs. Ann Medearis, Mr. Ernest Tucker, Mrs. Louise Smedden, Mr. Howard Kaufman, Mr. T. S. Lloyd, and Mr. Walt Edwards, dealer sales representatives, made therapeutic claims for Niagara devices for conditions not stated in the labeling.

The Government also moved for a preliminary injunction restraining Niagara Therapy Manufacturing Corp. from distributing 31 chair-type devices and 75 portable devices of various models (approx. 10 percent of the devices originally seized), on the grounds: that, unless such injunction issued, substantially all of the devices, originally seized would be distributed to the general public before the court could rule on the Government's motion for leave to file a Second Amended and Supplemental Complaint; that an in rem seizure action would become moot unless the court had control over the general public would create hardship for the Government, the general public, and Niagara. Accordingly, the court enjoined Niagara Therapy Manufacturing Corp.

On 9-9-66, the Second Amended Complaint was filed and specified devices were seized. Niagara Therapy Manufacturing Corp. of Brocton, N.Y., claimed the devices and consented to a decree of condemnation on the ground that they were misbranded while held for sale. The consent decree ordered the devices delivered to FDA for investigational and exhibit purposes. (121)

Pierce Ezes ear-piercing earrings, at Sarasota, M. Dist. Fla.

Charged 7-28-66: while held by Adco, Gold Products Div., Sarasota, Fla., the labeling of the article, which had been repacked by the dealer, lacked adequate directions for use and warnings against misuse, and it was not possible to write adequate directions and warnings for lay use; 502(f)(1) & (2). The article was claimed by Albert S. Drohlich, t/a Adco. The case was tried by the court without a jury. On 10-11-66, the court found, in part: that the article's instructions included cleansing the ear wire and the earlobe with alcohol or hydrogen peroxide; that adequate sanitation and sterilization procedures must be followed if earlobe piercing is to be accomplished

safely; and that neither hydrogen peroxide nor all types of alcohol were effective cleaning agents on the earlobe sufficient to prevent infection, nor were they effective against the spread of hepatitis. The court concluded that the article lacked adequate directions and warnings, and condemned the article. Upon motion of the claimant and without objection by FDA, the court authorized the articles released to the claimant for sale as earrings to persons with pierced ears. (122)

Tropic-Air heat exchanger, at Reading, E. Dist. Pa.

Charged 8-31-66: when shipped by Omnitech, Inc., Southbridge, Mass., and while held for sale by Pennsylvania Optical Co., Reading, Pa., the labeling contained false and misleading asthma and other lung ailment claims; 502(a). Default decree ordered destruction. (123)

PROPHYLACTICS

Rubber prophylactics, at Knoxville, E. Dist. Tenn.

Charged 12-7-66: when shipped by National Hygienic Products Corp., Dothan, Ala., the quality of the article labeled in part "Paramount Sales Co. Tested Preps Knox-ville" was deficient, since the article contained holes; 501(c). Default decree ordered destruction. (124)

Rubber prophylactics, Peacocks, 2 seizure actions at Greenfield, S. Dist. Ind., and Dallas, N. Dist. Tex.

Charged 6-22-66 and 2-24-67: when shipped by Dean Rubber Co., North Kansas City, Mo., the article's quality was deficient, since it contained holes; 501(c). Default decrees ordered destruction. (125)

Rubber prophylactics, Royal Knight and Seal Tite, at Elgin, N. Dist. Ill.

Charged 7-14-66: when shipped by Allied Latex Sales, Inc., Dothan, Ala., the articles' quality was deficient and their labeling was false and misleading, since the articles contained holes (approx. 1-5 percent); 501(c), 502(a). Default decree ordered destruction. (126)

NOTICES OF JUDGMENT on Criminal Cases

FOOD

Liberty Cash Grocers, Inc., Memphis, W. Dist. Tenn.

Charged 3-31-67: flour, rice, and dried beans were held in a building accessible to rodents, and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (127)

Mound City Grocery Co., and Edward Salzman, president, St. Louis, E. Dist. Mo.

Charged 4-5-67: wheat, cereal, and popcorn were held in a building accessible to insects, and were contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (128)

DRUGS

Leonard R. Calverley, Dallas, N. Dist. Tex.

Charged 11-2-66: amphetamine sulfate capsules, desoxyephedrine hydrochloride tablets, and secobarbital sodium capsules were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment suspended, fine, and probation. (129)

Cargill, Inc., t/a Nutrena Mills, Div. of Cargill, Inc., Peoria, S. Dist. Ill.

Charged 7-5-67: when shipped, Nutrena Creep-20 medicated feed was deficient in strength of penicillin and chlortetracycline; the conditions of the article's manufacture, processing, and packing lacked conformity with current good manufacturing practice; the labeling was false and misleading as to penicillin and chlortetracycline content and as to the article's adequacy and effectiveness against cervical abscesses and bacterial swine enteritis; and the article lacked an antibiotic certificate or release and was not exempted, since it was deficient in its medications; 501(a)(2)(B), 501(c), 502(a), 502(f)(1). When shipped, Nutrena Pig 30 medicated feed was deficient in strength of penicillin and chlortetracycline, and the conditions of the article's manufacture, processing, and packing lacked conformity with current good manufacturing practice; 501(a)(2)(B), 501(c). Nolo contendere plea; fine. (130)

Horton Bros. & Brown Drugs, a partnership, Grayson, E. Dist. Ky.

Charged 4-12-67: Equanil tablets and penicillin tablets were dispensed without a prescription; 503(b)(1). Guilty plea; fine, plus costs. (131)

Mervin G. Miller, prison officer, and Frances R. Ellington, waitress, Hutchinson, Dist. Kans.

Charged 12-20-66: amphetamine sulfate tablets were unlawfully possessed, sold, and delivered; and a complete and accurate record with respect to controlled drugs was not prepared, obtained, or kept; 301(q)(2), 301(q)(3), 301(q)(4). Not guilty pleas. After trial by court and jury, verdicts of guilty; imprisonment. (132)

William L. Rittenberry, t/a Rebel Truck Stop, Wentzville, E. Dist. Mo.

Charged 7-29-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment suspended, fine, and probation. (133)

Savage Laboratories, Inc., Houston, S. Dist. Tex.

Charged by grand jury 4-11-67: when shipped, the labeling of Neopavrin etheravrine injectable and Neopavrin etheravrine tablets was false and misleading in stating that the drug was essentially without side effects, and such labeling lacked adequate direction for use and was not exempted (certain uses of the drug may cause serious cardiac arrhythmia, including complete atrioventricular dissociation, intraventricular block, ventricular ectopic rhythms and flutter and fibrillation); and the labeling of the Neopavrin etheravrine injectable failed to warn adequately against unsafe dosages and unsafe methods of administration and application and unsafe duration of administration; 502(a), 502(f)(1), 502(f)(2). While held for sale, Adenosine B₁₂ Intramuscular injectable was labeled with labeling that contained false and misleading claims for bursitis and lacked adequate directions for use and was not exempted, since the labeling failed to warn against intravenous injections; 502(a), 502(f)(1). While held for sale, Libigen gonadotropin injectable was labeled with labeling that contained false and misleading claims for obesity, male impotence, climacteria and senility; 502(a). The firm, and an individual defendant against whom charges were subsequently dismissed, moved to dismiss the indictment. On 6-15-67, the court upheld the indictment saying:

"The court finds that the provisions of 21 U.S.C.A. 331 are constitutional and that the application of these provisions to the defendant Savage do not deny him of his constitutional right of due process.

"In view of the authorities discussed * * *, and the multitude of 'pure food and drug' statutes, State and federal, containing similar penal provisions and the cases upholding convictions pursuant to these statutes, the court finds that the provisions of 21 U.S.C.A. 333 (imprisonment for one year, a fine of \$1,000, or both) are not so disproportionate to the nature of the offense so as to constitute a cruel and unusual punishment.

"The defendants also challenge the indictment in this case on the basis that it fails to charge any offense with particularity. They rely principally on *Van Liew v. United States*, 321 F.2d 664 (5 CA 1963), to support this claim. * * * It is the opinion of this court that the indictment in the present case adequately apprises the defendants of the offenses with which they are charged. It defines the elements of the offenses charged and gives the defendants sufficient information so as to indicate to what extent a prior acquittal or conviction may be pleaded. See *Van Liew v. United States*, supra; *Beitai v. United States*, 306 F.2d 665 (5 CA 1962). The defendants complain in regard to Count One of the indictment that the government, in charging that the labeling was inadequate, failed to state what constitutes adequate labeling for the particular drug in dispute. This is not necessary. The government has specifically pointed out in what respects the labeling was inadequate. It need not further point out what might be considered a proper label. Similarly, in Count Two the defendants

challenge the indictment because 'unsafe dosages, unsafe methods of administration and application and unsafe duration of application' is vague. The indictment charges that the defendants 'failed to warn against unsafe dosages and unsafe methods of administration and application and against unsafe duration of administration.' Once again the government has set forth why the label is defective. How can the government enumerate 'unsafe dosages' * * * as the defendants demand? The acts complained of in this portion of the indictment are ones of omission. Finally, the defendants challenge the use of the phrase 'false and misleading' in Counts Three and Four. As is stated in *Van Liew v. United States*, supra, the use of these terms without further explanation is not satisfactory. The indictment in this case does inform the defendants as to why the government has characterized the label as 'false and misleading.' Count Three states that it is because the label indicates that the drug is effective in the treatment of bursitis. Count Four states that it is because the label indicates that the drug is effective in the treatment of obesity, male impotence, climacteria (sic) and senility. The court finds that the indictment is not defective for failing to charge the disputed offenses with particularity.

"Finally, the defendants allege that Counts Three and Four of the indictment fail to charge an offense under the Federal Food, Drug and Cosmetic Act. This is based on the fact that the labeling in dispute states only 'that it is reported' that the particular drugs are effective in treating certain diseases and conditions. The defendants contend that the use of this type of language does not state, represent or suggest that the drugs in question were adequate or effective in treating the enumerated diseases and conditions.

"The authorities are clear that the use of language as employed in the labeling of the drugs involved in this case is within the purview of the statute." Thereafter, guilty plea by Savage Laboratories, Inc.; fine. (134)

INJUNCTION ACTION

Bios Laboratories, Inc., Delta Chemical Works, Inc., Fred L. Rothschild, vice president, and Mrs. Peni K. Massey Hendrickson, office manager, New York, S. Dist. N.Y. Charged 11-15-62 in complaint for injunction: that the defendants were engaged in the production, labeling, promotion, and distribution in interstate commerce of approximately 18,000 chemical substances (some being drugs and some being hazardous substances) in containers suitable for household use; that such chemical substances were distributed for use by universities, chemical houses, research institutes, qualified investigators, and members of the general public; that in the absence of the president of the corporations, since his departure from the United States on or about 11-1-58, Rothschild and Massey acted as attorney and agent for the president; that, as policy, no orders for any chemical substance supplied by the defendants were turned down; that some orders were received by telephone, and some "come in on blank letterheads"; that if the chemical substance was listed in the defendants' catalogs, the defendants assumed that it was all right to sell such chemical substances to anyone who ordered; that one catalog listed: Mescaline Sulfate (a derivative of peyote), Chloral Hydrate (a derivative of chloral), Amphetamines (dangerous drugs), Cantharidin (a dangerous irritant and vesicant obtained from Cantharides/Spansish Fly), Stilbamidine and LSD (drugs not generally recognized as safe, which were undergoing investigational and experimental use), Tetraethylthiuram Disulfide and Butazolidin (New drugs with effective new drug application), Glycyocamine and Mersilid Phosphate (new drugs whose effective new drug applications had been suspended), Chloramphenicol and Penicillin (certifiable antibiotic drugs), Mercurous Chloride (an N.F. cathartic), Mercury Bichloride/Mercuric Chloride/Corrosive Sublimate (a U.S.P. disinfectant), Hydrogen Cyanide/Prussic Acid (a highly toxic substance), B-B-Dichloroethyl Sulfide/Mustard Gas (an irritant substance), and Hydrofluoric Acid (a corrosive substance); that a number of such drugs were being unlawfully shipped in interstate commerce by reason of: inadequate directions for use, inadequate warnings against unsafe use, failure to bear prescription legends, and being new drugs without effective approved New Drug Applications—502(f) (1 & 2), 503(b)(4), 505(a); and that a number of such hazardous substances were being unlawfully shipped in interstate commerce by reason of failure to bear required label statements—2(p)(1)(C, E, F, G, H, I & J). The defendants contended in part that the defendants just sold chemical substances to qualified firms and individuals; that the complaint only specified two shipments of cantharidin in 1958, two shipments of mescaline sulfate in 1961, and a single shipment of hydrofluoric acid in 1962; that the mescaline sulfate was labeled as being for investigational use only; that the shipments prior to 1959 were legally irrelevant; that the defendants were presently, and had been, long before, acting in accordance with the law; and that there was no basis for granting the relief sought. The defendants also contended that the petitioned for requirement of specified record systems was inequitable. After a hearing, the court found that a preliminary injunction should issue, saying that three or more violations were sufficient to invoke the equity powers of the court to assure that the public shall be protected against the broadcast of poisonous or hazardous substances. The injunction enjoined the shipment in interstate commerce of drugs or hazardous substances unless and until: (i) a specified record system was established, (ii) a qualified individual was employed to determine label compliance of drugs and hazardous substances, (iii) FDA was given free access to inspect.

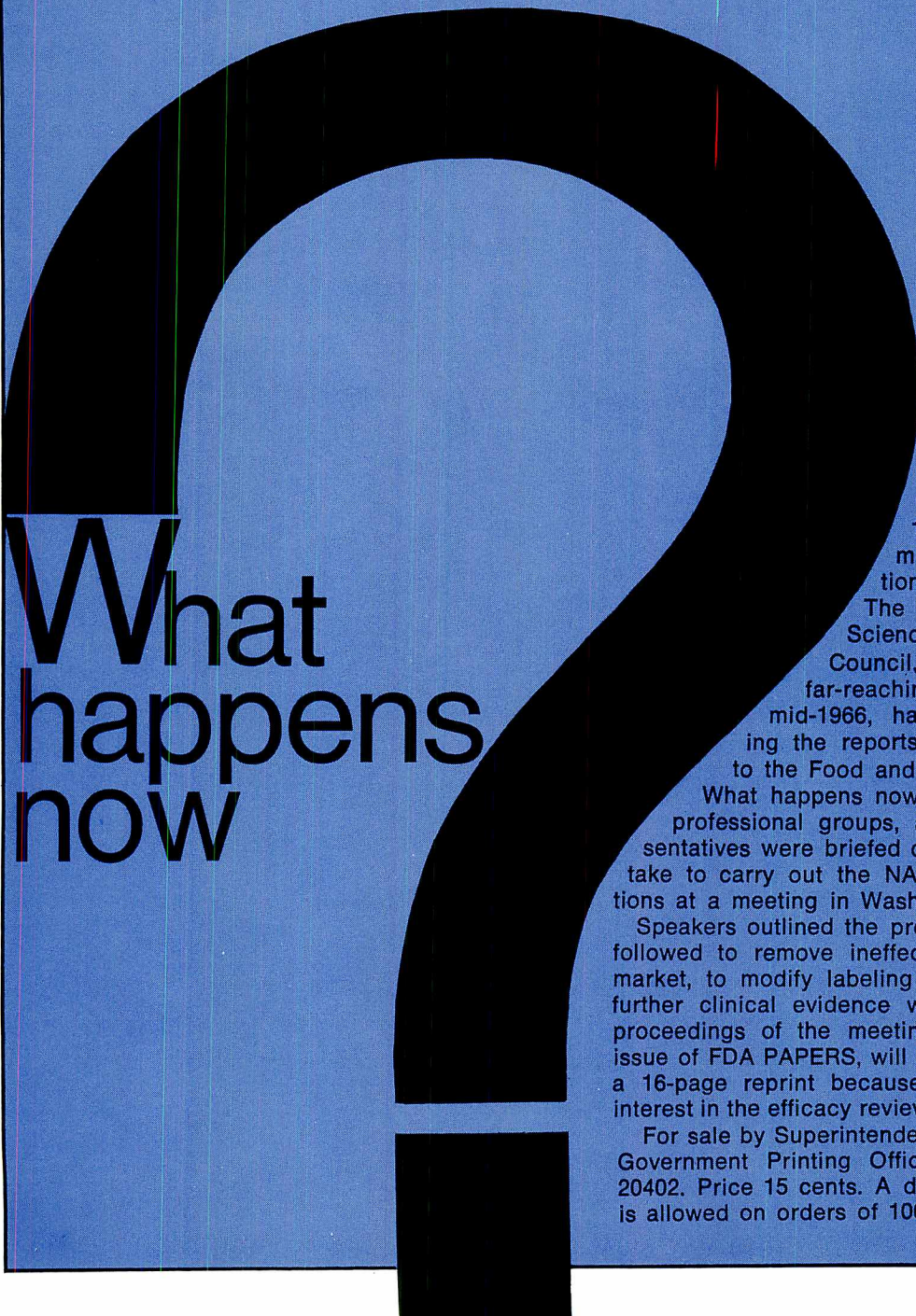
Charged 4-28-64 against Delta Chemical Works, Inc., and Mrs. Peni K. Massey Hendrickson, as criminal contempt of the above injunction: the failure to employ a qualified individual to determine label compliance of drugs and hazardous substances; the shipment of Oxalic Acid 10%, a hazardous substance lacking required statements; the shipment of three prescription drugs that lacked adequate directions for use and were not exempted; the shipment of four new drugs that lacked effective approved New Drug Applications; and the failure to establish the specified record system. The defendants moved to dismiss the charges on the grounds that the shipments charged had been made to an FDA agent; that the defendants were entrapped; that the shipments were consigned to a nonexistent firm; that the firm had employed both a graduate student, who had majored in chemistry and had a BA degree, and a pharmacist, who had been licensed and practicing since 1906; and that the individual defendant had, without success, made every effort to ascertain what were new drugs. After trial, the court found the defendants guilty of all the charges except the new drug charge, and fined the individual \$1,000 and the corporation \$10,000. (135)

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

Case summaries are prepared by Food and Drug Division, Office of the General Counsel, DHEW.

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

James L. Goddard, Commissioner of Food and Drugs
Washington, D.C., March 1, 1968



What happens now

The evaluation of the effectiveness of the roughly 3,000 new drugs put on the U.S. market from 1938 to 1962 is now moving into the "action" phase.

The National Academy of Sciences-National Research Council, which undertook the far-reaching efficacy review in mid-1966, has now begun sending the reports of its expert panels to the Food and Drug Administration. What happens now? The drug industry, professional groups, and consumer representatives were briefed on the steps FDA will take to carry out the NAS-NRC recommendations at a meeting in Washington January 23.

Speakers outlined the procedures that will be followed to remove ineffective drugs from the market, to modify labeling claims, or to obtain further clinical evidence when necessary. The proceedings of the meeting, published in this issue of FDA PAPERS, will be made available as a 16-page reprint because of the widespread interest in the efficacy review and its implications.

For sale by Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Price 15 cents. A discount of 25 percent is allowed on orders of 100 or more copies.

OFFICIAL BUSINESS

Announcements

COSMETIC SCIENCES CONFERENCE A conference on cosmetic sciences jointly sponsored by the Toilet Goods Association, the Society of Cosmetic Chemists, and the FDA will be held at the Washington Hilton Hotel, Washington, D. C., on April 22-23.

It will present results of current research in cosmetic science and give scientists of Government and industry an opportunity to discuss problems, programs, and developments. Various aspects of analytical and physical chemistry, toxicology, and microbiology will be treated in 17 research papers.

For further information, contact James H. Merritt, Toilet Goods Association, 1625 I St., N.W., Washington, D.C. 20006 or Jonas L. Bassen, FDA Bureau of Voluntary Compliance, 200 C St., S.W., Washington, D.C. 20204.

INSPECTIONAL REPORTS To promote voluntary compliance by industry, FDA District Offices are now issuing information letters to firms following plant inspections which reveal significant adverse conditions or practices which have caused or could lead to violations.

Issuance of such letters was initiated March 1 by the Bureau of Regulatory Compliance as a pilot program in response to industry suggestions at FDA-Industry workshops. The letters are expected to stimulate firms to bring about needed improvements.

To distinguish this information letter from the "warning letter" issued under Section 306 of the FDC Act, the following explanation is being sent with each letter:

"The attached letter applies to an inspection made of your establishment. It is not intended to imply that the Food and Drug Administration will, or will not, recommend any civil or criminal action. The letter in no way relieves your firm or its personnel from responsibility to take steps to insure compliance with the Federal Food, Drug, and Cosmetic Act. It is not intended as an all inclusive report on objectionable conditions. It must not be used in part or in whole in the promotion of your firm's product or facility."

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

SCHEDULE OF FDA WORKSHOPS AND REGIONAL CONFERENCES APRIL & MAY 1968

FDA District or BDAC Field Office	Date	Location	Subject Area
Chicago	April	(to be determined)	Salmonella—Analytical Methods and Procedures
	April	(to be determined)	Bacterial Contamination in Import Foods
Minneapolis	April	(to be determined)	Bacterial Contamination in Smoked Fish
New York	April	New York	Sanitation in the Spice Industry
	April (3rd week)	Puerto Rico	GMP—Drugs
Philadelphia	April	Philadelphia Area	Bacterial Contamination in Convenience Foods
San Francisco	April	San Francisco	Bacterial Contamination—Salmonella
Seattle	April	Alaska	Bacterial Contamination in Shellfish
	April	Alaska	Bacterial Contamination in Shellfish
Chicago	May	(to be determined)	GMP—Drugs
Los Angeles	May	California	Medicated Feeds
Minneapolis	May	(to be determined)	Fair Packaging and Labeling
Philadelphia	May	Philadelphia Area	Sanitation in Cocoa Bean Industry
	May	Philadelphia Area	GMP—Drugs
San Francisco	May	California	Medicated Feeds