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CONSUMER RELATIONS

An Interview with Maurine Neuberger

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Clinical Testing

Synopsis of the New Drug Regulations

FAIR PACKAGING AND LABELING ACT

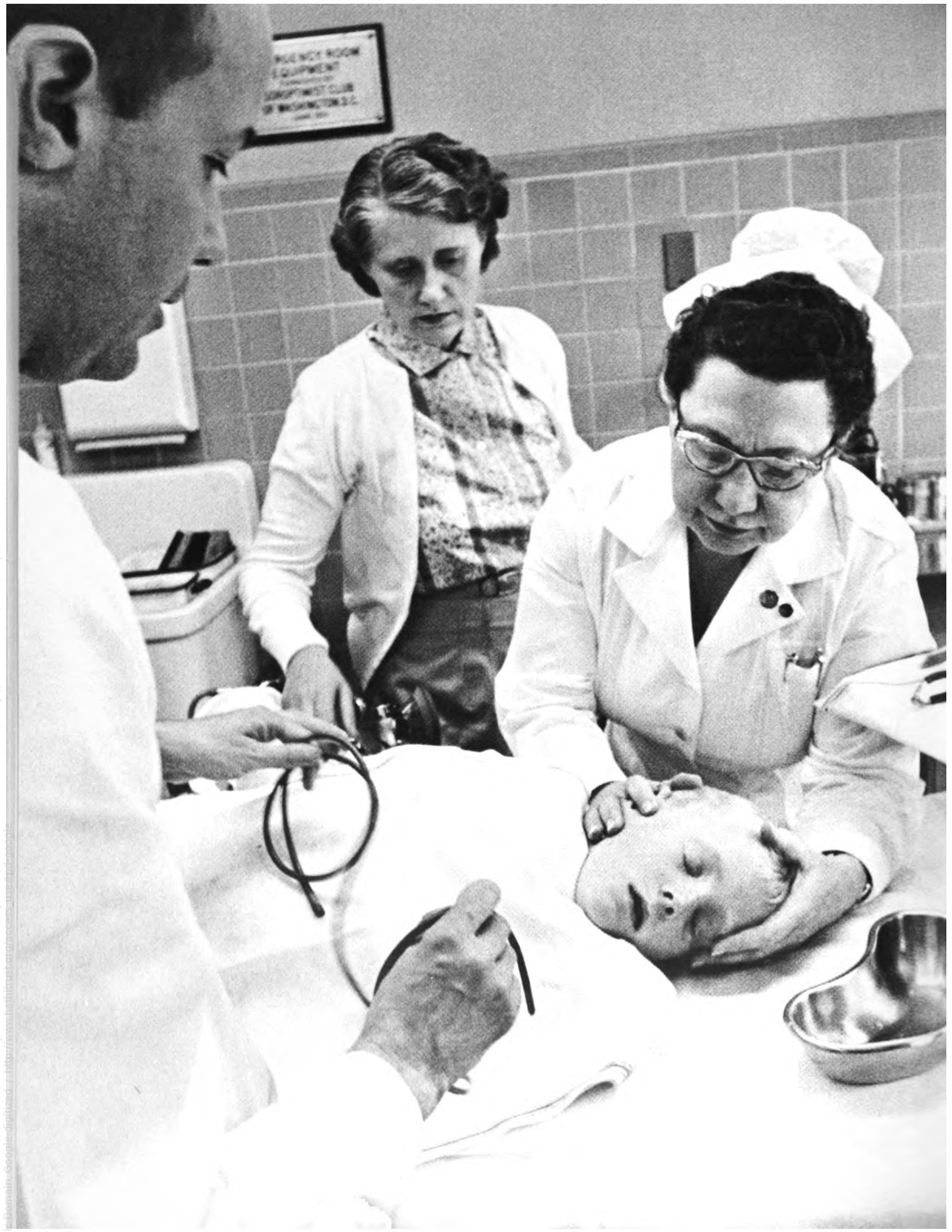
Issues we face

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*"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

A point has been made that statistics are lacking on deaths of children under five due to accidental ingestion of aspirin, aspirin-containing and other salicylate products. There is evidence of 125 deaths in 1964; half of the Nation's poison control centers reported more than 16,000 cases of accidental ingestion in 1965.

Whatever the number, it is a frightening experience for each and every parent. Each case gives the attending physician anxious moments. Each statistic imposes an unnecessary burden on the Nation's over-taxed health facilities.

It is encouraging to note that a united effort to reduce the hazard is now being mounted by leaders of the drug industry in collaboration with distinguished pediatricians. The voluntary packaging and labeling actions agreed to last November (see page 4) are being implemented by drug makers whose representatives have also had their first meeting with the pediatricians on safety packaging.

FDA is an interested observer of this effort which, it is hoped, will become a precedent for reduction or elimination of other health hazards through voluntary, united industry action in collaboration with medicine, and with the advice and consent of the Government.

quotes

“While it is generally accepted that there is some minimum number of organisms comprising an infectious dose of *Salmonella*, this minimum is uncertain and not predictable. The general health of the individual, his resistance to the organism, the manner in which the product is used, and several other variables are involved. We are advised by our medical experts that viable *Salmonella* in a product to be ingested constitutes a potential hazard to health.”

Kenneth R. Lennington, Salmonella Project Officer, to the Drug and Allied Product Guild Workshop, New York, January 25, 1967.

“We speak of quality, quality products, and quality controls without, at times, adequately understanding, appreciating, or defining the implication of the word ‘quality.’ . . . I use the word in the sense of ‘excellence.’ The dictionary defines quality as ‘character with respect to excellence or grade of excellence,’ and quality control as meaning checking and directing the degree or grade of excellence of processes and products. It implies to the drug manufacturer that every drug bearing the name of the firm requires a detailed system of methods, facilities, and controls covering manufacture, processing, packing, storage, and distribution in an adequately housed and well-equipped plant. It is the objective of such operations to produce drugs that are safe, effective, and pharmaceutically elegant. In this sense the good manufacturing practice regulations state the ground rules which must be observed for attainment of such excellence.

Earl L. Meyers, Ph.D., Bureau of Medicine, to the Drug Manufacturers-Repackers-Relabelers Workshop, Austin, Texas, February 22, 1967.

“Much of what is now regarded as quackery stems from a reluctance to discard procedures which were once accepted but have since been proven to be useless or even dangerous; that is, what was medically and scientifically accepted practices 100 or even 50 years ago may, to a large extent, be regarded as quackery today. Conversely, some folklore of bygone times has later been found to have a scientific basis.”

Harold F. O'Keefe, Food and Drug Officer, Bureau of Medicine, to the First National Congress on Chiropractic, January 13, 1967.

Ingestion of Consumer

Clinical

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

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Errata

On page 23, Patient Consent, the last paragraph is in error. A proposed regulation would remove the requirement of written consent in Phase 3 investigations. It is not yet effective. Interested persons have 30 days to comment on the proposal. Until the proposed regulation becomes effective the policy stated in the regulation of August 30, 1966 will continue in force.

FDA PAPERS

VOL. 1, NO. 2/MARCH 1967

Conference on Prevention of Accidental Salicylate Products by Children

Report on conference 4
held November 21, 1966, summary of major recommendations, and list of participants.

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her new role as Consultant on Consumer Relations to Commissioner Goddard.

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Synopsis of the New Drug Regulations. This is an effort to clarify and explain the 21
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Section 705 [375] of the Food, Drug, and Cosmetic Act.

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

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

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

Top industry leaders, distinguished physicians, and FDA officials gathered for a unique conference last November 21 in Washington. It was unique because: (1) they had specific problems to discuss and resolve, and (2) they were motivated by the suggestion of a congressional committee. The subject was:

prevention of accidental ingestion

In the background were several points considered by the Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce during its autumn hearings on the Child Safety Act of 1966: each day U.S. industry manufactures 25 tons of aspirin; during 1965 over 16,000 children under 5 years of age accidentally ingested aspirin and other salicylates; more than 10,000 cases involved flavored "children's" aspirin; while 125 deaths due to aspirin and other salicylates were reported in 1964, accurate records of deaths due to "children's" and "adult" aspirin are not available.

The committee had considered further limitation of the 50-tablet bottle of children's aspirin. It was noted that this limitation followed the recommendation of an FDA medical-industry advisory panel in 1955. Another primary consideration was safety packaging of children's aspirin. The committee

noted that "industry representatives indicated a willingness . . . to abide by recommendations for further limiting the quantity of children's aspirin in a retail container if a new advisory panel . . . concluded that such a limitation would reduce serious illness and death. . . ."

The House Committee's suggestion led to the 1-day conference sponsored by FDA and attended by drug makers, physicians, public health specialists, and FDA officials.

Commissioner James L. Goddard, M.D., was host to the group and Dr. Harry Shirkey from the Committee on Drugs of the American Academy of Pediatrics, and Director of The Children's Hospital of Birmingham, served as chairman. In opening the meeting Dr. Goddard stated that the first and major agenda item was how to accomplish the fact of limitation of total grainage of aspirin in a retail package. "Congress suggested in a very direct fashion that we hold

this conference," said Dr. Goddard, "and if the problem could not be solved on a voluntary basis that they would be willing then to entertain legislation at a future date."

Early in the meeting the group reviewed the size of the individual children's aspirin tablet, which for many years has been generally standardized at 1¼ grains. Dr. Edward Press offered a motion that the group agree to "stick with 1¼-grain tablets for flavored children's aspirin."

Dr. Press's motion to limit the size of flavored aspirin tablets to the 1¼-grain size was adopted. The group further adopted a resolution that "we are opposed to prohibiting the manufacture of flavored aspirin."

Irving Sunshine, Ph.D., Cuyahoga County, Ohio Coroner's Office, pointed out that vital statistics records are inadequate—that they do not usually show whether children die from eating too many children's aspirin or adult aspirin,



of salicylate products by children

and it is important to recognize this. He said, "We are in ignorance here and we should somewhere along the line try to get some knowledge." Dr. Shirkey added: "We have spoken glibly about this . . . and we have accepted data and used terminology rather loosely."

Dr. Maurice L. Tainter said, "May I point out in the 125 deaths (of children under 5 in 1964) there are only 4 specifically stated to be from baby aspirin. There were, however, 56 cases where the kind of aspirin was not specified. And under the head of 'Other Salicylates' there were 47 deaths . . . where there was no further indication of what the nature of it was or whether it was an aspirin or some other salicylate. . . ."

Dr. Press proposed that "the Na-

tional Office of Vital Statistics be formally requested to attempt to deliberately gather additional factual information . . . on the cases of salicylate deaths, particularly in children under five where the presumption of accident is much higher"

Henry L. Verhulst said that 341 poison centers—a little more than half of those in the Nation—reported that 16,328 children ingested aspirin during 1965. He also said that data on fatalities showed a minimum dosage of 31 grains taken by a 16-month-old child. "That was the minimum," he said, "most of them (fatalities) involved 50 or 60 grains."

Dr. Tainter reviewed data from the medical literature on mortality in preschool children from all causes, home accidents, and poison-

ings due to aspirin, other salicylates, and other substances; on incidence of accidental ingestion due to various salicylate products; and factors involved in poisoning, such as therapeutic overdosage, storage, repeater problem.

He pointed out that a surprising proportion of children involved in accidental poisonings are repeaters—among reports of 700 children the percentage of repeaters ran as high as 28 percent. Also salicylate poisoning due to therapeutic overdosage, through error on the part of parents or medical personnel, was noted to be significant. In several studies from the literature this averaged 39 percent, and in the 125 deaths in children under 5 years occurring in 1964, according to Dr. Tainter, there were 17 cases of therapeutic overdosage.

Dr. Tainter pointed out other characteristics seen in childhood poisonings. In 2/3 of the cases in one study the tablets or bottles were not in their usual place; 13 percent of the children found as-

pirin on the ground; 25 percent and 32 percent found the bottle on an open shelf. The figures varied in different studies. Dr. Tainter said that parental carelessness certainly is involved in such cases.

In an attempt to determine the minimum lethal dose, he cited literature cases reporting age and dosage wherein 85-90 grains appeared to be the minimum fatal dose. On the other hand, applying the figure of 140 grains as being the toxic dose of aspirin for an adult—the comparable toxic dose for a 2-year-old of 12.4-kg. body weight would be 47 grains or 38 1½-grain tablets.

Dr. Press presented statistics on accidental ingestion of aspirin from Poison Control Centers of downstate Illinois and Chicago for 1965. In downstate Illinois there were 3,653 cases of aspirin ingestion, of which 2,967 were from children's aspirin, 408 from adult aspirin, and 278 not specified as to children's or adult. In Chicago there were 1,590 cases of aspirin ingestion, of which 1,184 were specified as children's aspirin, 70 as adult aspirin, and 336 unspecified. In 1,712 cases involving children's aspirin where information was available concerning amount taken, 970 took 25 tablets or more. Of 35 deaths due to aspirin over the last 5 years in Chicago, nine were ascribed to children's aspirin and four of these were due to therapeutic overdosage.

Dr. Alan K. Done presented a study of 500 of the most recent consecutive cases of aspirin ingestion appearing at the University of Utah Teaching Hospital over a 2-year period. The study included only children under 5 years of age, and only children for which information was available as to whether they took children's or adult aspirin. He said that many of these children took up to 50 tablets (1½ grain) and had no symptoms; however, all but one were treated within 4 hours.

Another group of youngsters not

treated early, developed moderate intoxication when taking more than 45 (1½ grain) tablets. Dr. Done said, "We were surprised to find no severe cases among the children who took children's aspirin . . . all of our severe cases . . . took the adult (5 grain) variety instead. The question of how many children's aspirin would seem . . . to be safe in a single container depends upon the severity of poisoning that one is willing to accept. I personally am not willing to accept

the absence of death as the end point we ought to be striving for. . . . I would suggest from these data at least, that the allowable number of children's aspirin (1½ grain) per bottle be about 35 or 36.

"Of these 500 cases, 13 percent involved adults' and 87 percent children's tablets . . . I think these data indicate clearly as far as these 500 cases go . . . that the adult aspirin is certainly more dangerous in individual cases and that whatever danger is entailed in the en-

*Summary of FDA Conference
on Prevention of Accidental Ingestion
of Salicylate Products by Children*

*Arlington, Virginia
21 November 1966*

Free, open, and vigorous, but cooperative discussion was entered into by the practicing and teaching representatives of medicine, members from industry, and members of F.D.A. The discussion covered all salicylate-containing products packaged for retail sale to the public.

Only some points were determined after motion and voting and are identified (V). Many points were gained by consensus.

It was understood from the representatives of industry that they could assure 100% cooperation by the packagers and dispensers of aspirin-containing products for over-the-counter sales in implementing decisions made by this group.

The significant decisions were these:

- (V) (1) The smaller aspirin tablets, often referred to as "children's aspirin" tablets, shall continue as gr. 1½ in size.*
- (V) (2) The group was opposed to prohibiting the flavoring of "children's aspirin."*
- (3) It was against flavoring 5 grain aspirin tablets ("adult aspirin tablets").*
- (4) The maximum number of gr. 1½ tablets permitted for a retail container would be 36.*
- (5) Manufacturers would not ship out retail packages containing a number more than 36 tablets after June 1, 1967. Dr. Goddard assured all that the present bottle size (to contain less tablets) would be permitted.*
- (6) It was recognized that an ideal safety closure would be desirable for aspirin and all drugs if possible (O.T.C. and prescription). Previous and continuing efforts in producing safety closures were recognized. A committee was appointed to make a continuing study of improved safety closures for "children's" and "adult" aspirin-containing tablets. Members: Dr. Edward Press, Chairman, Dr. Jay M. Arena, A member from Glass Container Industry, A member from Sterling Drug, Inc., A member from Plough, Inc., A member from Bristol-Myers Co., A member from Drug and Allied Products Guild, A mem-*

ticement brought about by the flavoring of children's aspirin would appear to be more than over-weighted . . . by the smaller dose in the pills . . . I think I would be forced to conclude . . . that it would be irrational to exclude adult aspirin and other salicylates from any safety campaign that is aimed at children's aspirin."

Dr. Done said they were surprised to find that parents whose children took adult aspirin tended to come into the hospital later than

those who took children's aspirin. He suggested that it might be advisable to warn parents of the dangers of relatively small numbers of adult aspirin. "It was quite apparent from these data the people whose children took 4 aspirin weren't nearly as scared as those whose children took 40 aspirin, irrespective of the children's variety or the adult variety."

After Dr. Done's presentation and the ensuing discussion, the group voted to limit the number

of 1½-grain flavored children's aspirin to 36 in retail packages. The group also agreed to make special efforts to disseminate information so that small manufacturers or manufacturers of the future would have no difficulty in discovering the recommended limitations. Industry representatives agreed that 36-tablet bottles could be on the market by June 1, 1967. In order to insure meeting this deadline, the FDA agreed to permit use of the same size bottle which previously held 50 tablets. It was also agreed that this would permit use of same-size labels to bear appropriate warnings.

The participants then explored problems associated with safety packaging for both children's and adult aspirin. Safety closures and strip packaging were the most frequently mentioned possibilities. "I think this is deserving of a special study group," said Mr. Richard Fisher. "Certainly the glass container and closure industries . . . are wholeheartedly at the disposal of this conference. . . ." Harry B. Solmsom stated that Plough, Inc., was desirous of working with any group that might be appointed, "and we will be glad to make available to them our files and whatever information that they determine would be helpful." Dr. Press agreed to be chairman of a safety-closure committee, which will be made up of representatives from the drug industry, glass containers and closure industry, and the medical profession.

Dr. Allan B. Coleman put particular emphasis on the packaging of adult 5-grain tablets. He said, "I would like to see . . . a recommendation . . . that 5-grain aspirin tablets be packaged in a safer manner than they are now . . . since 5-grain aspirin tablets tend to be in homes in packages of 100 or 250 or sometimes a thousand they are extremely dangerous . . ."

The group agreed in a consensus statement to urge the manufacturers of 5-grain aspirin tablets to develop safe packaging for their

ber from Whitehall Laboratories. A strong feeling was expressed in favor of attention to the safety closure feature of strip packaging.

- (7) Agreement was reached for labeling all aspirin-containing products intended for children and for adults. This would include carton and container label and would read (in heavy block type on clearly contrasting background) "Warning, keep this and all medicines out of children's reach." "In case of accidental overdose, contact a physician immediately."*
- (8) Oil of Wintergreen, methyl salicylate, was recognized as a frequently lethal agent when ingested accidentally. Concern was also expressed about poisoning by phenyl salicylate and other toxic salicylates. FDA agreed to again bring this problem to the attention of the manufacturers of these products.*
- (9) The F.D.A. was asked and agreed to attempt to obtain a more detailed delineation of which deaths from salicylates were from methyl salicylate or from aspirin intended for adults or children. It was agreed that present data from the National Office of Vital Statistics is insufficient.*
- (10) Educational programs should point out the dangers of accidental ingestion of "adult" aspirin, "children's" aspirin, and therapeutic overdosage. Industry pointed out that the Council on Family Health would be active in educational programs for the public to point out dangers from misuse of salicylates, other drugs and hazardous substances, as well as accidents in general.*
- (11) It was agreed that advertising to the public with undue emphasis on flavor, and without warning against accidental ingestion, is undesirable.*
- (12) It was recommended that this study group or similar body reconvene in the near future to evaluate the status of O.T.C. salicylates.*
- (13) It was agreed that the conclusions of this group be widely publicized in the Federal Register and elsewhere.*

*Respectfully submitted,
Harry C. Shirley, M.D.
Chairman*

HCS:vr

products. At the suggestion of Dr. Edward Press, the recommendation for safety packaging was extended to include prescription drugs. However, it was pointed out by William M. Bristol, III, that the packaging problems for OTC products are separate from those for prescription drugs. Dr. Press and Dr. Shirkey agreed that this would necessarily entail a campaign to the retail druggist and the pharmaceutical drug industry.

All major manufacturers at the meeting agreed to a new warning label soon to be on all aspirin bottles: "Warning: Keep this and all medicines out of children's reach." The label also recommends in case of accidental overdose a physician should be contacted immediately.

In considering other safety measures to prevent injury or death, it was urged that medical directors carefully review advertising. Dr. Arena said, "I think that the industry certainly does know the value of television for selling their products and they can certainly use this media for selling safety for their products. . . ." Industry's efforts in education of the public through the Council on Family Health were recognized.

Near the conclusion of the meeting, Dr. Samuel C. Southard, past chairman of the Committee on Accident Prevention, American Academy of Pediatrics, called for a self-regulatory mechanism within the industry. This organization would follow up recommendations of the study group and in a sense would be the manufacturers' own

police force. However, the group did not act upon this suggestion.

Dr. Shirkey strongly suggested that this group, or a similarly constituted one, be reconvened at a later date to discuss the progress and problems associated with aspirin-containing products.

In concluding the meeting, Dr. Goddard called the seminar "constructive" and said that the FDA would maintain surveillance. He expressed optimism "that we will make additional progress in the months and, hopefully, the years ahead." In commenting on Dr. Southard's suggestion, he said, "I recognize the point that was brought up. There is need for continued surveillance because new ideas crop up from time to time, and I, too, have the feeling that industry should take the initiative."

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an interview with Maurine Neuberger



Former Senator Maurine B. Neuberger became Consultant on Consumer Relations to the Commissioner of Food and Drugs on January 6, 1967. Mrs. Neuberger will advise the Commissioner on broad-scale programs and policies in various areas of consumer needs.

The widow of Senator Richard L. Neuberger, she was elected in 1960 to fill out his unexpired term and to serve a full 6-year term, which ended January 3, 1967.

During her years in the Senate, Mrs. Neuberger took an active interest in the protection of the American consumer and in the activities of the Food and Drug Administration.

Senator Neuberger served on the Senate's Special Committee on Aging, including its Subcommittees on Fraud and Health and Joint Subcommittee on Long-Term Care, and the Committee on Commerce.

The former Senator has published numerous articles in national magazines on consumer affairs and on national health care and welfare. She is the author of the book, *Smoke Screen: Tobacco and the Public Welfare*, published in 1964.

Mrs. Neuberger's first action as consultant was a program-planning session in San Francisco with eight FDA consumer specialists.

She made her first public appearance in her new FDA role as the keynote speaker at the Annual Convention of the Association of California Consumers in San Francisco on February 11.

Q. Mrs. Neuberger, after serving 6 years in Washington, how do you feel about being just a consumer again?

A. It has been a tremendously rewarding experience to have served in the U.S. Senate, and I must say it

was with some regret that I bade my colleagues goodbye. However, I would like to emphasize that there is no such thing as being "just a consumer." I always felt that I was a consumer at the same time I was a Senator, and I am a consumer now in my new home in Massachusetts. We must remember that the consumer is the fundamental agent in our expanding economy. The purchase of goods and services and the rate at which those purchases are made determines the kind of economy we are going to have and the kind of standard of living we are going to have, so the question of being "just a consumer" is really not the proper way of looking at it.

Q. President Johnson in his state of the Union message said, "The 88th and 89th Congresses enacted more social and economic legislation than any two Congresses in our history. But all of this legislation will come to nothing unless it reaches the people." I wonder how you react to that statement and what comments you might want to make.

A. The President is quite right. As a participant in those two Congresses, I still recall with a thrill the work of our committees and the tremendous effort put forth by the Administrative Branch. I must say that the problem of making this legislation effective rests not solely with the Federal or State or local governments. It does rest with all elements of our society concerned with the health and well-being of all Americans. I'm thinking, for example, of our physicians and of our pharmacists, our dentists, our nurses, and other professional personnel. I'm thinking of our great industries, such as pharmaceuticals, foods, cosmetics and those other non-governmental groups who work cooperatively with governmental agencies. These groups share the task of implementing the legislation passed by the 88th and 89th Congresses.

Q. How would you describe your job as Consultant on Consumer Relations?

A. It was made clear in conversations between Dr. Goddard and me that I would not speak for the FDA. I would speak for the consumer to the FDA. The establishment of this precedent is a very good one for the Food and Drug Administration and I'm very proud to have the privilege of exploring this new kind of activity. I will advise the Commissioner on matters of consumer needs as I see them; I'll bring them to his attention. They may or may not always be relevant to the kinds of responsibilities the FDA has to carry out, but I see myself as the voice of the consumer at the highest administrative level of the FDA. It is with this understanding that I took the position and it's with this understanding that I'm looking forward to carrying it out.

Q. In that sense would you say that the consumer has an obligation to himself to be informed in order to be protected in the marketplace?

A. The consumer does have that obligation but I don't believe that he is always aware of it. He has to be reminded of it continually. As you know, I've been associated with many issues in the area of health that really demanded of the consumer that he keep himself informed, such as the relationship between cigarette smoking and lung cancer, the effects of fluorides in preventing caries, and the place of supplements in diet.

Q. Senator, you have served on the Senate Subcommittee on Frauds and Deceptions Affecting the Elderly. What are your views on FDA relations with the aging?

A. In the FDA you will find a number of responsibilities which I think are directly related to the elderly. For example, I think the FDA program on insuring the quality and integrity of drugs in the marketplace is of prime interest to our elderly citizens. They now have vastly improved medical programs at their service and are encouraged to use many of the newer therapeutic agents, as well as the old standbys. The second thing is a wholesome food supply. In addition, there must be assurance that commodities are marketed, packaged, and labeled so that the buyer can determine what is the best value. Within a limited income there is a tremendous variety of food stuffs available. Third, it is the FDA which protects the elderly from frauds and deceptions. For instance—FDA's campaign in combating device and nutritional quackery. Dr. Goddard has said that this campaign will be maintained and strengthened.

Q. Mrs. Neuberger, during hearings by your Senate committee, representatives of the food, drug, and cosmetic industries testified that there was a direct relationship between the success of products in the marketplace and the satisfaction of the consumer. Would you comment on this in light of the Fair Packaging and Labeling Act?

A. There is some merit to the argument that every time a consumer buys a product he is casting a vote for that product. However, the Fair Packaging and Labeling legislation was enacted to make sure that the consumer was able to cast an informed vote.

Q. Mrs. Neuberger, your assignment to the FDA is part-time, what other public activities will you carry on?

A. I am National Chairman of the Advisory Council on the Status of Women and will continue to serve in that capacity at the same time as I work for the FDA.

Running- awayness



This new FDA publication deals with the "generation gap" and the abuse of drugs by adolescents for runningawayness. Its message: ". . . . Escape through excessive use of drugs is a pathological response to social and economic pressures, physical, and emotional pains. . . . There are now legal controls over certain stimulants, sedatives, and hallucinogenic drugs, and there must be effective enforcement of the law. But there must also be education and psychological understanding. . . ."

Runningawayness, FDA Publication No. 38, will be published soon. Order from the Superintendent of Documents, U. S. Government Printing Office, Washington, D. C. 20402; price will be announced later.

the issues we face in carrying out the fair packaging and labeling act

by William W. Goodrich

Few measures have promised so much as the Fair Packaging and Labeling Act. It is popularly known as the Truth-in-Packaging Law. The consuming public has high expectations that, because of it, better packaging and more informative labeling will appear in the very near future—about July 1, 1967.

The President, in signing this bill, said that it would help the housewife save money; that it would target labels that lie and packages that confuse; that it would restore truth in the market place. The new law, he said, is to tell the consumer exactly what is in the package, who made it, how much it contains, and how much it costs in comparison with competitive packages. And, he said, it will eliminate the need for a slide rule as a shopping aid, free the consumer from uncertainty in making buying choices, and protect her from being shortchanged by a slack-filled box.

The January issue of *Changing Times* magazine reports that new government measures are about ready for announcement, with the result that package labels for foods, drugs, and cosmetics will soon be easier to read and will tell you more. "The Months Ahead"

column headlines that help is coming to the shopper; that she can say goodbye to the "Jumbo-Pound" and the "Giant Quart"; that slack-fill practices are soon to be eliminated; and that "cents-off" sales soon will be stringently regulated.

Our goals are thus defined; and for those of us who must mold the regulations to fulfill the promise of this new law, and satisfy the reasonable expectations of the purchasing public, busy days lie just ahead.

The time for talking generalities is over, and we must now begin to deal with the specifics of labeling and packaging reform.

While the bill was strongly supported in the Congress by consumer interests, and just as strongly opposed by the regulated industries, it emerged from the House Committee hearings with unanimous support, and it passed both Houses of the Congress with hardly a dissenting vote.

Thus, everyone apparently wants labeling and packaging changes as soon as possible.

We now face the test as to whether the regulations called for by the bill can be swiftly devised and placed into effect, or whether protracted procedural delays will block early implementation.

Here is a brief summary of what is in this new law and how we are directed to proceed:

First, there are mandatory provisions for agency regulations.

We are directed to require—

That the label identify the product and give the name and address of its manufacturer, packer, or distributor;

That the net quantity of contents be separately and accurately placed at a uniform location on the principal display panel; and

That any label which says anything about servings, also says how much is in each serving.

Since the existing law for food, drugs, and cosmetics has long required the name of the product, and the name and address of its manufacturer, packer, or distributor, we should focus our attention here on the quantity of contents provisions. These will require a basic overhaul of essentially all existing labels. And while this is taking place, we should give attention to all required label information—whether called for by this new law or by existing law.

The quantity of contents statement will have to have several new features:

It must be a distinct part of the principal display panel;

For many packages, it must contain a dual statement of total ounces,



and pounds and ounces or quarts, pints, and ounces, identified as avoirdupois or fluid ounces, together with fractional ounces in common or decimal fractions;

It must be conspicuous, easily legible, and in distinct contrast with other matter on the label;

Its type size must bear a fixed relationship to the area of the principal display panel;

The declaration must be in uniform type size for all packages of substantially the same size; and

The declaration must be generally parallel to the base of the package as it is to be displayed.

This is saying a lot. In a sentence, it means that the quantity of contents statement must become an important design feature of the principal part of the label.

We must decide where it shall appear—at the top left of the label, the top right, top center, immediately above or below the most prominent feature of the label, or at some other uniform place.

We must decide how large the print will have to be, and how the required conspicuousness, legibility, and contrast are to be achieved.

And we must have uniformity in type size for all packages of essentially the same size, even though they may have different sized labels.

Foods, drugs, and cosmetics already bear net contents statements,



but now one must search several label panels to find them. And even where voluntary improvements have been made to meet rising criticism, front panel placement, uniformity, and improved contrast will no doubt call for yet another change.

As an example of what might be required, we may look to the labeling requirements for hazardous substances. Our regulations call for the signal word and the statement of principal hazard to be placed on the principal panel, distinctly apart from other wording or designs, and for prominence to be achieved by placement within the borders of a square or rectangle, with or without a border line. We require suitable contrasts of background, achieved by distinctive typography or color or both. We specify the minimum point size for type, and we require a reasonable relationship with other label type on the front panel.

These are some of the possibilities for the net contents statements.

What of other mandatory labeling declarations required by the newly enacted law and by existing law?

Does the name and address of the manufacturer, packer, or distribu-

tor, or the serving information, required by the new law, or the ingredient information called for by existing law, also belong on the front of the package? If not, where does it go, and what considerations of prominence, conspicuousness, type size, and contrast will control?

Can, and should, exemptions be made for quantity of contents declarations for small packages?

When do we call for weight declarations, as against a declaration by numerical count? When do we require avoirdupois ounces and when fluid ounces?

What additional supplemental statements as to quantity of contents will be permitted elsewhere on the label? As for example, that the product makes one pint, or a three-layer cake?

Are express prohibitions required to eliminate the "giant quart"?

These are illustrative of our problems in taking the first step in the long journey to satisfy the promise of the new law.

But this is not all.

We are authorized to make some exemptions from full compliance with the law to the extent that such compliance is impracticable or unnecessary, and to impose conditions on such exemptions.

Whenever necessary to prevent

deception or to facilitate value comparisons, regulations are to be prescribed—

Establishing standards for "large," and "small," and "economy" sizes of packages;

Regulating, but not prohibiting, "cents-off" and other bargain promotions;

Requiring additional ingredient information on drugs and cosmetics, without divulging trade secrets; and
Preventing nonfunctional slack-fill.

Of all this, perhaps the most urgent are the controls over "cents-off" promotions and slack-filling. And perhaps the most controversial will be ingredient labeling for cosmetics.

Only recently, representatives of a large coffee distributor called on us to urge prompt action on "cents-off" promotions. According to these representatives, their company had stopped the practice at the time of the recent Federal Trade Commission investigation, only to see an immediate loss of business to competitors who did not stop. In short, they contended that this kind of competition was essential to survival, so long as any important competitors were allowed to use it.

The Congress recognized, as did we all, that most Americans are bargain hunters. And the job set before us is to see that the promise



of reduced price is not an illusory one; to see that, insofar as possible, any offer of "cents-off" is actually delivered to the consumer.

The guidelines we have are found in the House Committee report. We are told that the regulations may, for example, require a showing by the manufacturer that the wholesale price has been reduced enough to permit retailers to pass the "cents-off" saving on to the consumer. The regulations may limit the duration and the frequency of such promotions, and they may fix the maximum percentage of the annual output that may be marketed with "cents-off" labeling.



William W. Goodrich, Assistant General Counsel, Food & Drug Division, U.S. Department of Health, Education, & Welfare, presented this paper on January 24, 1967 to the New York State Bar Association.

All of this requires an oversight of pricing practices, which is an entirely new function for the FDA. Indeed, in our most extensive inspection authority—that over the marketing of prescription drugs—we are not allowed access to "pricing data." But we will have to examine pricing practices to carry out the obligation to make "cents-off" offers real price reductions.

Controlling slack-filled packages has, thus far, been a difficult operation for FDA. Operating under a law that declares misbranded any package so made, formed, or filled as to be misleading, FDA has been notably unsuccessful in the courts. About all our efforts have yielded is a rule of decision to the effect that a person using a package too big for its contents may justify this apparent deception by proving that it is necessary to safeguard the product and that no less deceptive, alternative method of packing is available.

S. 985, the Senate-passed bill, did not contain authority to prohibit slack-filling. Instead, it provided for package standardization when proliferation of package sizes was likely to impair the consumer's ability to make price-per-unit com-

parisons. And the bill provided that such standards should not preclude the use of packages customarily used for related products of varying densities, except to the extent that continued use was likely to deceive.

These standardization provisions—even though largely voluntary under that bill—were the rallying points for industry opposition. And their elimination by the House Committee in favor of completely voluntary actions to eliminate confusing package sizes opened the way to the final enactment of the measure.

The House bill, H.R. 15440, contained authority to prevent the distribution of packages of sizes, shapes, or dimensions likely to deceive consumers.

This provision was not supported by administration proponents. Nonetheless, the House Committee retained a slightly modified slack-fill provision. The agencies were authorized to prevent nonfunctional slack-filling of packages—defined as filling the packages to less than capacity for reasons other than the necessities of protecting the contents, or the requirements of machine filling. So the agencies have authority to prevent such practices as the use of false bottoms



or unnecessarily bulky packaging material.

The House Committee report is wholly consistent with the judicial rule that the burden will be upon the user of a package that is too large for its contents to justify its use.

Much has been said about the label declaration of ingredients for cosmetics. The original Hart bill contained provisions which would have required label declaration of composition for consumer commodities in general. As passed by the Senate, the bill called for regulations to require, consistent with the requirements of the Federal Food, Drug, and Cosmetic Act, composition information other than proprietary trade secrets. It was argued that this excluded the authority to require label declaration of cosmetic ingredients because the Federal Food, Drug, and Cosmetic Act did not require it. But, again, the House Committee made its intentions clear—that cosmetic ingredient information could and should be required to assist the consumer in making value comparisons.

But nothing in this entire law can take effect until regulations are first promulgated.

And these regulations are to be

adopted through the elaborate public procedures for formal rule-making found in the Federal Food, Drug, and Cosmetic Act.

They begin with a notice of proposed rule-making. After comments are received, the rules are adopted. Then objections by any person who will be adversely affected may stay the effectiveness of the rules and precipitate a public hearing on the objections. After the hearing, a decision is to be made on the record, and it is subject to judicial review in the United States Courts of Appeals.

These hearing procedures and the opportunity for judicial review assure protection to the rights of manufacturers, packers, and distributors of consumer commodities. But they also have an important bearing on how promptly the public can expect to benefit from improved labeling and packaging practices. Hearings and review on the net weight regulations alone could cause protracted delays.

There will, no doubt, be very good arguments why the net weight statement should not be at the top of the front panel, at the bottom, on the right, or on the left. Labelers can undoubtedly show the costs involved in making labeling

changes, the difficulties involved in redesigning packages, and that the new requirements will interfere with established brand labeling.

One need look no further than existing packages to see that there is no consensus about how or where to present the net contents declaration. And the same is true as to most of the other issues that must be solved before this new law can have its intended effect.

But the public is expecting substantial changes—for the better. It expects these changes to show up about July 1, 1967.

We plan to announce very soon the initial draft of regulations dealing with the mandatory aspects of the new law—net weight, name of commodity, name and address of the manufacturer, packer, or distributor, and labeling as to servings.

We hope to obtain a cross-section of views on which acceptable regulations can be promulgated and placed into effect by or shortly after July 1.

There is much to be done, and we must work together if the needs of manufacturers and consumers are to be reconciled within a reasonable time.

We will have to have the full cooperation of the affected industries to meet this deadline.



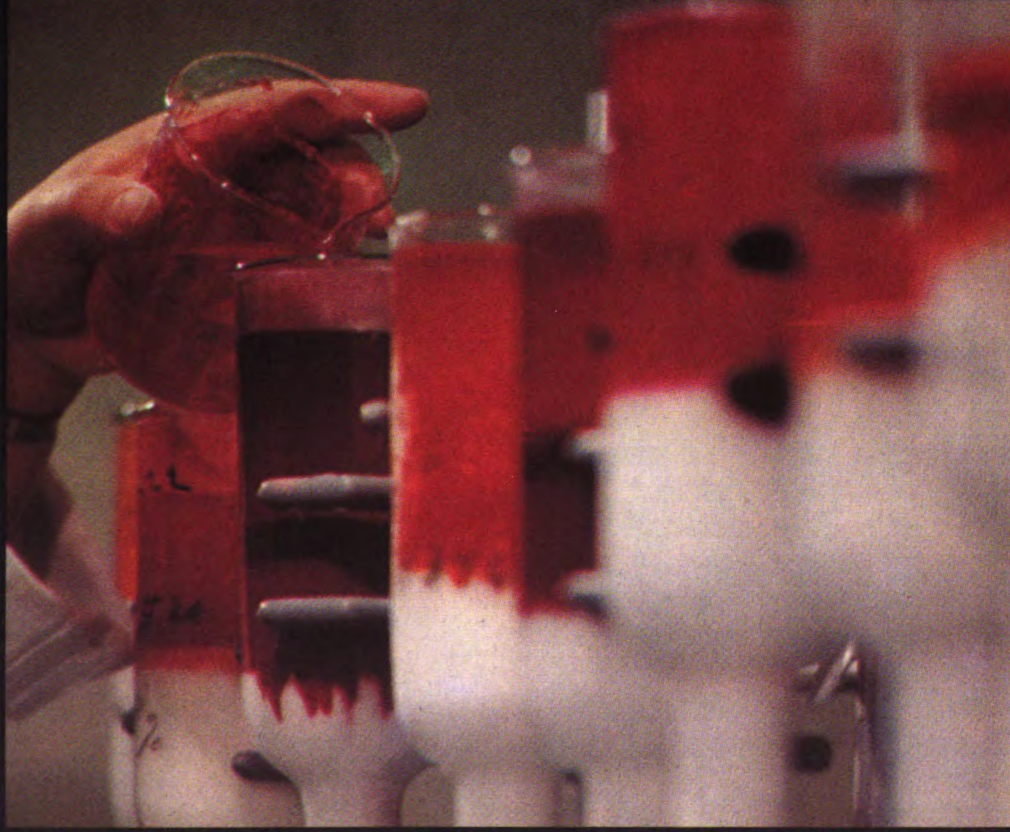
color additive certification

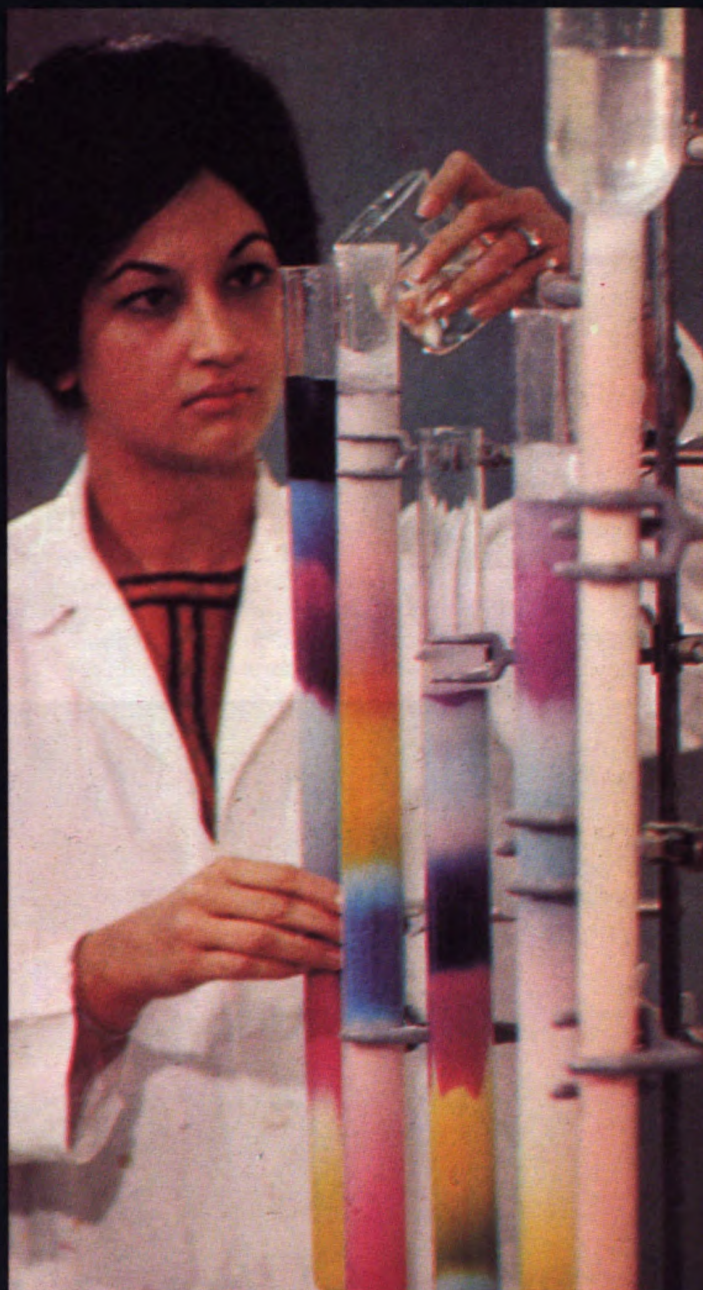
The Color Additive Amendments of 1960 provides that all color additives must be listed before they can be used in foods, drugs, or cosmetics. In order to be listed, proponents of the listing must produce convincing evidence that the color additive is safe for its intended use.

Under the Act, the Commissioner is empowered to require batch certification of color additives, or to exempt color additives from the certification requirement. FDA's color certification program is devoted primarily to the chemical examination of representative samples of each batch of color additives subject to certification. At the time of listing, specifications are established for each color. If laboratory examination shows that the specifications are met, a certificate is issued; if not, a certificate is denied.

Research is conducted to develop methods where needed and to improve existing ones. Research is also conducted on many facets of color additive chemistry. For example, do reactions occur when a color additive is used in a food, drug, or cosmetic; and if reactions do occur, what products are formed?

Approximately 1,700 samples representing 3.5 million pounds of color additives are examined each year by scientists in FDA's laboratories.

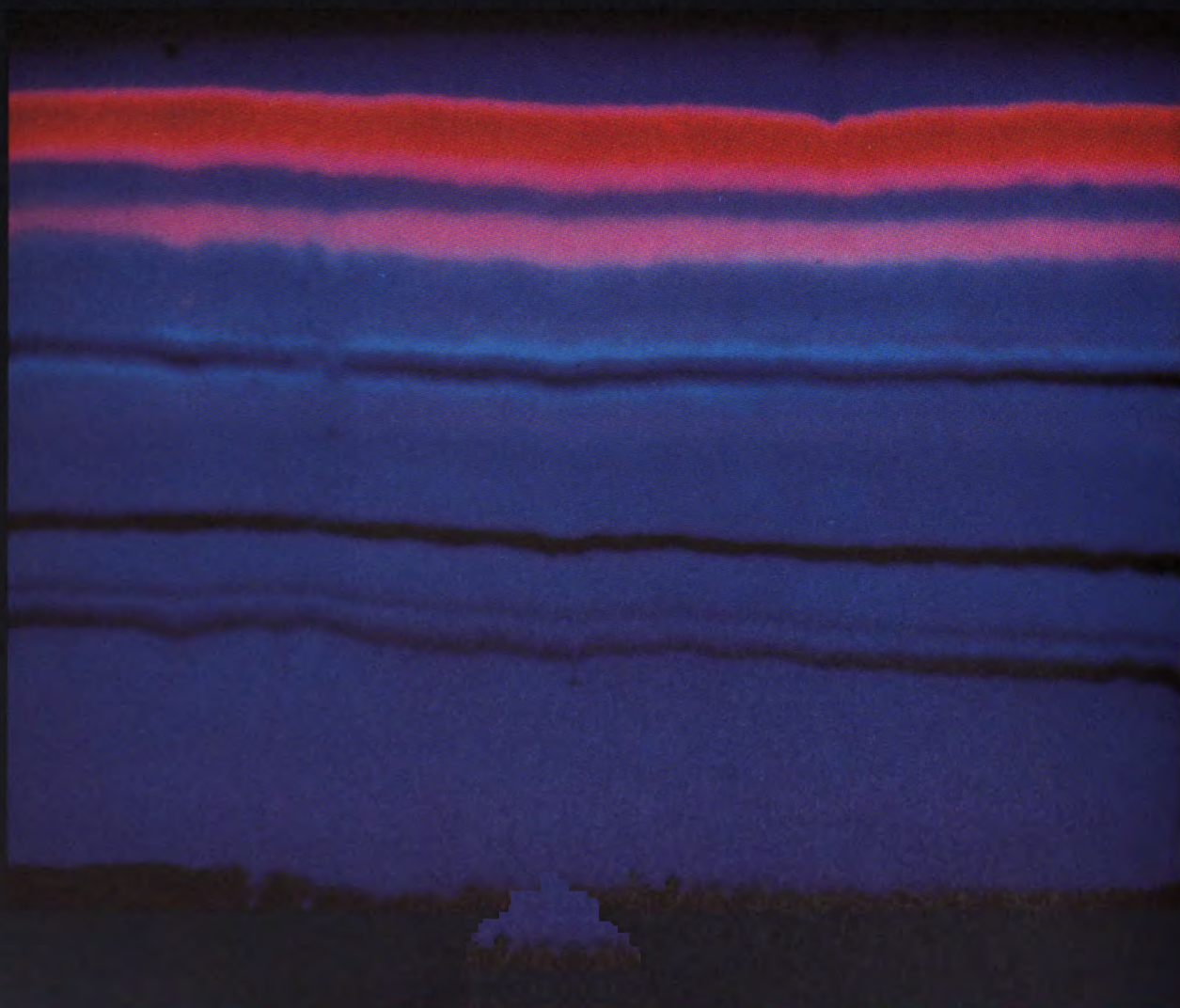




A wide range of chemical and physical procedures are used in the certification program. They range from simple weighing, through complex chromatographic and X-ray techniques. Column chromatography (above) separates colors for identification and determination of the amount of each. Pure dye determination (left) is accomplished by titration using titanium trichloride. (lower left) Separation of intermediates by column chromatography for analysis by ultraviolet spectrophotometer. Potentiometric titrimeter (upper left) is used to determine salt content of a batch of color. Samples are prepared (upper right) and diluted.



Heavy metals, such as lead and arsenic, which may be present in batches of color are detected (left) by X-ray fluorescence. Colored disks, foreground, are subjected to X-rays. Instrument, background, counts metal atoms in parts per million. Lipstick colors (below) are identified on thin-layer chromatographic plate under ultra-violet light. Bottom line, drawn by lipstick, produces lines of colors in mixture. This sample shows mixture of five colors. Each can be identified and checked for certification.



Clinical Testing

Synopsis of the New Drug Regulations

The 1962 amendments to the Federal Food, Drug, and Cosmetic Act strengthen the regulatory authority of the Government over clinical testing of new drugs in order to minimize hazards inherent in new drug development and to assure a responsible concern for the well-being of human subjects. Furthermore, the new regulations establish a strong basis for promotion of improved methods and evaluation of standards in investigation of new drugs.

This synopsis outlines the physician's responsibilities, under the Act, to the patients, to the pharmaceutical company, and to the Food and Drug Administration.

Definition of a New Drug

A new drug cannot be distributed interstate for use in man, without approval by the Food and Drug Administration. An exemption is required to permit clinical investigation.

Unless a drug is generally recognized by qualified experts as being safe and effective for the use proposed, it must be regarded as a "new drug." If there is uncertainty, the FDA will furnish its judgment on request.

A drug may be "new" without necessarily being a new substance. For example, if aspirin tablets were labeled or promoted as a seasickness remedy, they would be considered a "new drug." Even an accepted remedy, used for years, if manufactured in a new form, such as a timed-release capsule, is considered to be a new drug requiring evaluation by the FDA. Clinical investigation may be required to show that the active substance is released in a slow and sustained manner, and that the capsule is safe and effective as claimed.

First Steps in the Assessment of a New Drug: "IND"

Before a new drug may be tested on human beings, the "sponsor" (usually a pharmaceutical firm, sometimes an investigator) must supply to the FDA the information specified as a "Notice of Claimed Investigational Exemption for a New Drug" (Form FD 1571), known as an "IND." Copies of these IND forms are contained in the Investigational Drug Regulations, which may be obtained on request.

The IND is usually required to include, among other things, the following information:

- a) Complete composition of the drug, its source, and manufacturing information, adequate to show that appropriate standards exist to insure safety.
- b) Results of all preclinical investigations, including animal studies. Initially, these should be directed toward defining its *safety*, rather than its efficacy. The data must demonstrate that there will not be unreasonable hazard in initiating studies in human beings. Further animal studies may be conducted concurrently with clinical studies. The Bureau of Medicine will, on request, comment on the adequacy of proposed animal studies. The FDA generally requires as a minimum that acute toxicity be determined in two species of animals, that results of administration of the drug for two to four weeks be observed in at least two species, and that the route of administration be that which will be used in the human trials. Additional animal studies are frequently necessary.
- c) A description of the investigations to be undertaken.
- d) Information regarding training and experience of the investigators. (See "Qualifications of Investigators" below.) Investigators are responsible to the sponsor and are required to submit, to the *sponsor* (not the FDA), either Form FD 1572 for clinical pharmacology or Form FD 1573 for clinical trial.
- e) Copies of all informational material supplied to each investigator. (The type of information is listed in Form FD 1571.)
- f) An agreement from the sponsor to notify the FDA and all investigators if any adverse effects arise during either the animal or human tests.
- g) Certification that "informed consent" will be obtained from the subjects or patients to whom the drug will be given.
- h) Agreement to submit annual progress reports.

Physician-Sponsored IND

When an investigator wishes to act as sponsor for the use of a drug solely as a research tool or for early clinical investigation of a drug of therapeutic or diagnostic potential (clinical pharmacology—phases 1 and 2) a simpler abbreviated form of submission is acceptable. An example would be the study of a drug

that no manufacturer is interested in sponsoring. An outline of such a study should provide the following information:

1. The identity of the compound or compounds, together with the facts that satisfy the investigator that the agent may be justifiably administered to man as intended.
2. The purpose of the use and the general protocol.
3. Appropriate background information, including a brief statement of the investigator's scientific training and experience and the nature of the facilities available to him.



The physician sponsoring this form of IND deals directly with the FDA and is responsible for compliance with the procedures set forth in this synopsis.

Phases of Clinical Investigation

The first two phases are described as clinical pharmacology.

In the *first phase*, the drug may be administered to healthy volunteers, the object being to determine toxicity, metabolism, absorption and elimination, other pharmacological action, preferred route of ad-

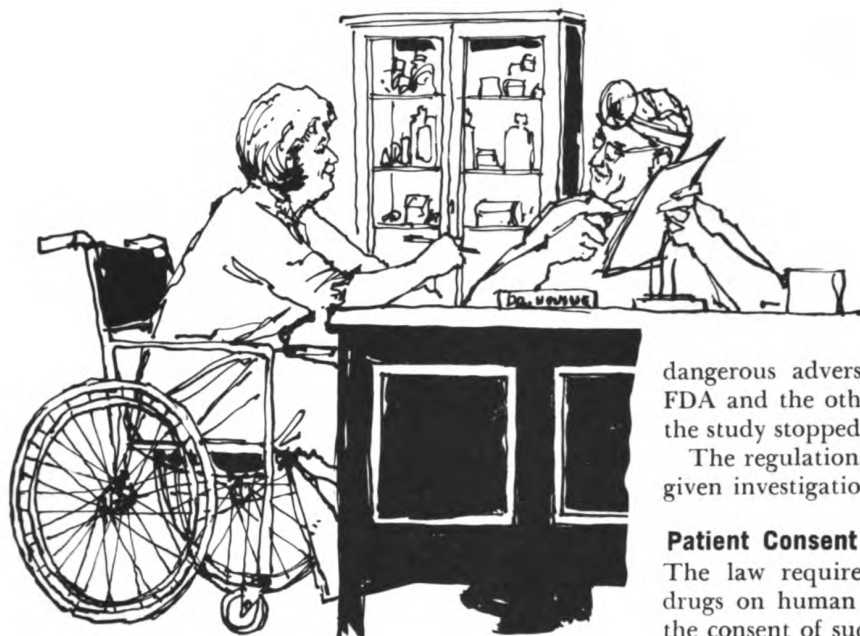
ministration, and safe dosage range. Such studies involve a comparatively small number of subjects and are ordinarily conducted under carefully controlled circumstances by persons with training in clinical pharmacology. The proposed clinical plan may allow considerable flexibility.

When phase 1 demonstrates satisfactory results, the sponsor may proceed to *phase 2*: initial trials in the treatment or prevention of the disease for which the drug is intended, in which the drug is administered to carefully supervised patients to determine safety and effectiveness. Additional pharmacologic studies, performed concurrently in animals, may be necessary to indicate safety for the phase 2 extension of the investigation.

The FDA is always willing to consider reasonable amendments to clinical plans and to discuss with sponsors the value of proposed studies. Of course, a plan of investigation may be revised during its course, but in each such instance the FDA must be notified.

Finally, if the data obtained in phases 1 and 2 provide reasonable assurance of safety and effectiveness or suggest that the drug may have a potential value outweighing its hazards, proposals for *phase 3*, or extensive clinical trials, are in order. Phase 3 may, where practical, involve, in addition to work by experienced investigators, well-controlled studies by other groups including practicing physicians whose training and experience in drug evaluation has been less, and whose facilities may not be so elaborate. The studies should be carefully monitored, no matter how extensive. The regulations are designed to prevent exposure to risk of an unnecessarily large number of patients by requiring assurance of safety based on earlier studies.

Once an IND has been submitted, the investigation may then proceed, unless the FDA presents an objection. If there appears to be an unwarranted hazard in the continuation of the ongoing clinical studies, the sponsor may be requested to modify or discontinue clinical testing until further preclinical work has been done. An important function of FDA reviews is to inform the sponsor regarding further investigation required before extending the clinical testing to another phase.



Qualifications of Investigators

The sponsor of an investigational new drug (usually the manufacturer) will ask the clinical investigator to supply the following information on Form FD 1572 (for the clinical pharmacologist engaged in phase 1 or 2 trials) or Form FD 1573 (for the physician engaged in phase 3 clinical trials):

1. A statement of his education, training and experience which qualify him. ("Curriculum Vitae.")
2. Information regarding the hospital or other medical institution where the investigations will be conducted, special equipment and other facilities.

The training and experience needed will vary, depending upon the kind of drug and the nature of the investigation. In phase 1, the investigator must be able to evaluate human toxicology and pharmacology. In phase 2, the clinicians should be familiar with the conditions to be treated, the drugs used in these conditions and the methods of their evaluation. In phase 3, in addition to experienced clinical investigators, physicians not regarded as specialists in any particular field of medicine may serve as investigators. At this stage, a large number of patients may be treated by different physicians so that a broad background of experience may be secured.

Obligations of Investigators

The investigator must keep careful records of his study and retain them for at least two years after completion. The records must be made available promptly to the drug sponsor and to the FDA when required. Progress reports must be sent to the sponsor (in practice usually the manufacturer) at intervals not exceeding one year.

Emergency reports must be sent to the sponsor when

dangerous adverse effects are observed, so that the FDA and the other investigators can be notified, and the study stopped if the hazard warrants.

The regulations regarding consent of human beings given investigational drugs must be observed.

Patient Consent

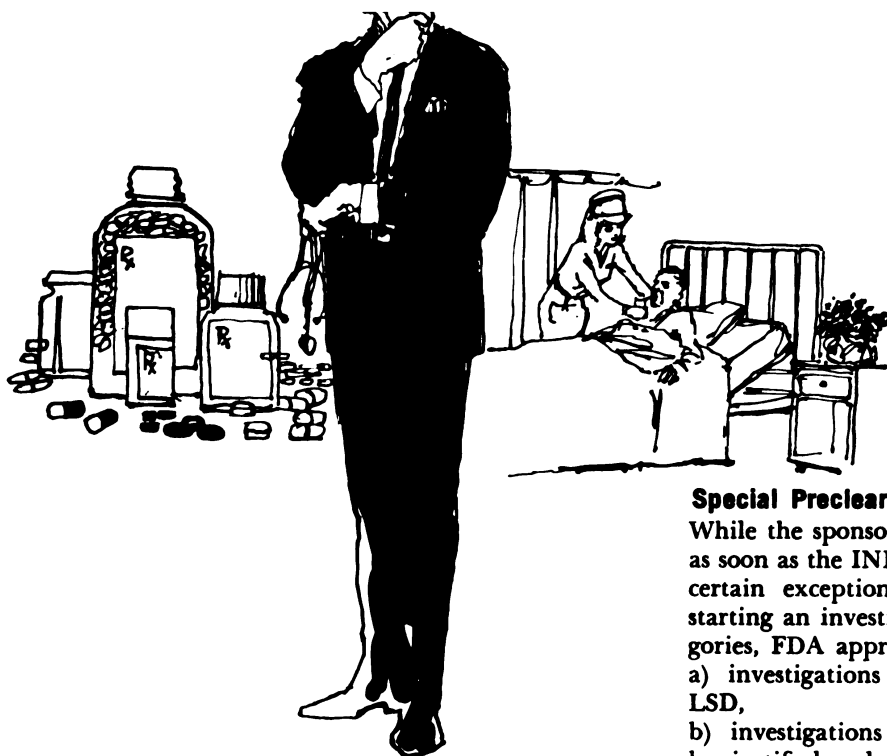
The law requires that before using investigational drugs on human beings, the physician must "obtain the consent of such human beings or their representatives except when it is not feasible or when in his professional judgment it is contrary to the best interest of such human beings." This means that the consent of persons (or the consent of their representatives) to whom investigational drugs are administered primarily for the accumulation of scientific knowledge must always be obtained; where patients are given a new drug for *treatment*, consent must also be obtained in all but exceptional cases. These exceptions are defined in the law as situations "where it is not feasible to obtain the patient's consent or the consent of his representative or where as a matter of professional judgment exercised in the best interest of a particular patient under the investigator's care it would be contrary to the patient's welfare to obtain his consent."

The consent for use of an investigational new drug in phase 1 and phase 2 must be in writing; in phase 3 it is the responsibility of the investigator, taking into consideration the physical and mental state of the patient, to decide when it is necessary or preferable to obtain consent in other than written form. If written consent is not obtained, the investigator must obtain oral consent except as provided above, and record that fact in the medical record of the person receiving the drug.

Causes for Termination of Investigation

The FDA may direct the sponsor to terminate an investigation at any stage under stated conditions. These include:

- Evidence of significant hazard.
- Convincing evidence that the drug is ineffective.
- Submission of false data.
- Omission of material information.
- Unsatisfactory manufacturing practices.



Failure to conduct the investigation in accordance with the plan submitted by the sponsor and approved by the FDA.

Commercialization of the drug. The IND regulations are not intended to provide a way of marketing a drug for profit without an approved NDA.

Failure to submit progress reports at intervals not exceeding one year.

Failure to report serious or potentially serious adverse reactions.

Failure to meet requirements for patient consent.

The Commissioner may notify the sponsor of any of the above conditions and invite immediate correction. A conference may be arranged. If the corrections are not effected immediately, the Commissioner may require the sponsor to terminate the investigation and recall unused supplies of the drug. The drug in question may not be reintroduced into clinical testing in man until additional data have been submitted to the FDA and the Commissioner has approved the proposed resumption of the study.

The Investigator and "Promotion"

The regulations forbid manufacturers or any persons acting for or on their behalf to disseminate any promotional material concerning a new drug prior to completion of the investigation. This is not intended to restrict the full exchange of scientific findings in scientific or lay communications media; its sole intent is to restrict promotional claims by the sponsor until the safety and effectiveness of the investigational drug have been established. Violation of the regulations by an investigator may result in FDA action to deny him further supplies of the drug; the manufacturer may also jeopardize *his* right to sponsor the investigation.

Special Preclearance before Human Trials

While the sponsor may ordinarily inaugurate a study as soon as the IND is submitted to the FDA, there are certain exceptions calling for preclearance. *Before* starting an investigation in any of the following categories, FDA approval is required.

- a) investigations of hallucinogenic drugs, such as LSD,
- b) investigations of drugs so toxic that their use may be justified only under special conditions, such as DMSO,
- c) reinstitution of drug investigations which had been terminated by the Commissioner.

Use of Drugs for Laboratory Procedures

New drugs used only for studies in vitro or in laboratory animals are exempted from the new-drug provisions of the Act provided they are labeled "Caution—Contains a new drug for investigational use only in laboratory research animals, or for tests in vitro. Not for use in humans."

The exemption does not apply, however, for a new drug used in vitro when this use will influence the diagnosis or treatment of disease in a human patient—for example, discs to determine the sensitivity to anti-



biotics of bacteria in culture, or a stick or strip of paper incorporating a reagent to test for sugar in the urine. Apparent ineffectiveness of an antibiotic sensitivity disc or a false negative test for glycosuria might well lead to an incorrect diagnosis and deprive the patient of appropriate treatment.

Before such a preparation can be marketed there must be certification (in the case of antibiotics) or approval of a New Drug Application (in the case of other drugs). For that reason, it is necessary to submit adequate proof of the effectiveness of these preparations before they can be marketed.

New Drug Application: "NDA"

After the human pharmacological and clinical studies previously described have been made, and the manufacturer is convinced that the new drug is safe and effective, he submits a New Drug Application ("NDA"), on Form FD-356 with supporting data and proposed labeling to show that "it could fairly and responsibly be concluded by qualified experts that the drug is safe and will have the effect it purports or is represented to have under conditions of use prescribed, recommended or suggested in the proposed labeling."

If the investigational new drug studies were well conducted, step by step, through each phase of investigation, the FDA would have in its hands at the end of phase 3 the complete information needed for an NDA which could be promptly approved. In practice, however, this has frequently not been true.

The FDA is required to act on the Application within 180 days. FDA action takes one of the following forms:

- 1) If the NDA is "complete," it will be approved, and may be marketed.
- 2) If the NDA is considered "incomplete" in certain specified respects (such as inadequate clinical data to demonstrate safety or efficacy), the manufacturer will be so informed. He may "complete" the application by submitting the lacking data.

Should the manufacturer disagree with the conclusions of the professional staff of the Bureau of Medicine, he may request conferences for discussion of the data which has been regarded as deficient. In case



approval is still withheld, the manufacturer is entitled to an administrative hearing, if he chooses to protest the judgment. Furthermore, a negative ruling following a hearing may be appealed to the courts.

Antibiotics and Insulin Preparations

New antibiotic drugs, and any new preparation of insulin, are also subject to the usual IND procedures. When the sponsor of an antibiotic considers the IND investigations sufficient evidence of a safe, effective product, he submits an Application for Certification which is reviewed by the Bureau of Medicine. For a new insulin product, he submits an NDA. After the antibiotic or insulin is "approved," a sample of each batch must be submitted by the manufacturer for tests to assure the identity, strength, quality, and purity of the product.

Surveillance of New Drugs on the Market

The responsibilities of the manufacturer do not end when a new drug has finally been approved for marketing. The manufacturer is required to send reports to the FDA every three months during the first year, every six months for the second year, and annually thereafter. These periodic reports must include information concerning current clinical studies, the quantity of the drug distributed, and copies of mailing pieces, labeling, and, if a prescription drug, advertising. Prompt reports (within fifteen days) are required of unexpected side effects, injury, toxicity or sensitivity reactions made known to the manufacturer. "Immediate" reports are required in case of drug mix-ups, evidence of contamination, or failure of the drug to exert its expected pharmacologic effect.

ATLANTA DISTRICT The Sherwood Candy Co., Atlanta, Ga., a partnership, and Albert J. Plunkett, partner and active manager, were each fined for holding food in a building accessible to rodents and insects, and for the presence of rodent urine and cockroaches in food products. Inspections of the firm's operations during the past have shown numerous insanitary conditions. During each inspection the conditions found were reported to the management with suggestions for corrections.

ATLANTA BDAC Sales of LSD accounted for the arrest of seven men in three different cases in Florida recently.

Ex-University of Florida students Robert Kenneth Davis, Sergio Luis Abreu, Kerry Wolfe Mulford, and Lawrence Yoeman were arrested on December 6 in Gainesville. The arrests followed investigation by a BDAC Agent in cooperation with the Florida Bureau of Narcotics.

Following buys of LSD and DMT by a BDAC Agent and a marijuana purchase by a Florida Bureau of Narcotics Agent, Richard David Retblatt was arrested on December 12 in Fort Lauderdale.

Edward (Fast Eddy) Kirschbaum and Michael Zukerman were arrested in Fort Lauderdale on December 11 for selling LSD and marijuana. Arrests followed delivery of 99 LSD cubes to a BDAC Agent. The case also involved delivery of LSD to a minor.

BALTIMORE DISTRICT Goff P. Lilly, M.D., Charleston, W. Va., was fined \$1,000 and placed on probation for 1 year on December 1 for selling prescription drugs without a proper doctor-patient relationship.

Teething pearls filled with a fluid containing viable micro-organisms were seized in Grafton, W. Va., on December 15. The vinyl rings shipped by Duo-Pac, Inc., New York, N.Y., were valued at \$1,400.

Since nonnutritive sweeteners had been substituted for nutritive sweeteners, FDA recently instituted seizure of orange and grape beverage concentrates. The concentrates, manufactured by DCA Food Industries, Inc., Ellicott City, Md., and repackaged and shipped by Cumberland Packing Co., Brooklyn, N.Y., were valued at \$23,360.

BUFFALO DISTRICT Goods voluntarily destroyed in the District during December included eye ointment

with excessive metal particles and an antibiotic with defects in the syringe. Zemmer Co., Oakmont, Pa., the manufacturer, destroyed approximately \$9,000 worth of ophthalmic ointment which it had recalled. G. C. Hanford Manufacturing Co., Syracuse, N.Y., destroyed 56,000 syringes of Super Mastol on December 8 because of defects in the syringe which allowed the medication to leak out.

CHICAGO DISTRICT False and misleading claims by G.R.I. Pharmaceuticals, Inc., Chicago, Ill., led to large-scale seizures of a vitamin-mineral supplement and an analgesic.

The products, Over-Fifty Capsulets and R-T-C Tablets, were manufactured by firms outside of Illinois, but repacked and misbranded with accompanying literature by G.R.I., a mail-order distributor.

Seizure was made on December 29 of products and literature valued at \$382,900.

Over-Fifty Capsulets were labeled as "a vitamin-mineral supplement to meet the needs of adults over fifty and all members of their family who have a vitamin-mineral deficiency." R-T-C Tablets consisted of three different types of tablets, each with a different analgesic-containing formulation for morning, afternoon, and bedtime use. Accompanying promotional material falsely represented that the product would provide 24-hour relief from the pain and discomfort of headaches, neuralgia, lumbago, arthritis, rheumatism, etc., and would maintain tissue supplies of vitamin C.

CINCINNATI DISTRICT For shipping misbranded amphetamine sulfate tablets in interstate commerce, a Tennessee man was sentenced to a year in jail on December 19. Floyd S. Foreman, trading as Darigon Corp., Knoxville, will serve the sentence concurrently with another 1-year sentence he received earlier for failing to register as a manufacturer of drugs. Apparently all of his production went into illegal channels. Detection of the plant cleared the way for prosecution of a number of "bennie" peddlers.

DALLAS DISTRICT The first sanitation workshop in the Nation for food warehousemen was held in Dallas on December 13. The District co-sponsored the workshop with the Texas Wholesale Grocers Association. Cooperating organizations were the Fish and Wildlife Service, U. S. Department of Interior, and the National Pest Control Association. The 98 food ware-

housemen attending learned about the following topics: FDA's philosophy of enforcement and warehouse inspections; control of birds, rodents, and insects in food warehouses; and inventory control.

The District recently detained imports of coffee and cheese valued at \$415,000. Coffee shipped from Angola and Guinea and valued at \$75,000 was detained because of rodent excreta and insect contamination. Colby cheese from New Zealand was detained because of adulteration with chlorinated pesticide residues.

DALLAS BDAC For selling LSD, Donald Wayne Frizzell, Dallas, Tex., was sentenced to a year in jail on December 16. Frizzell was out on parole on a 2-year sentence for unlawfully entering the United States without registering as a drug user. This conviction caused the revocation of his parole. He will be required to serve the remaining 18 months of the old sentence after completing the new sentence. In addition, on December 14, he was indicted by a Federal grand jury on two counts of selling heroin.

DENVER DISTRICT To further *Salmonella* control efforts, the Utah Health Department will hold monthly meetings in Salt Lake City for all Federal, State, and city health authorities. Participants will discuss current outbreaks of *Salmonella* infections and plan remedial measures to minimize further outbreaks.

The District also has started a program to supply the Utah Department of Agriculture with copies of the District's monthly work plans for Utah. State officials review FDA's planned activities and coordinate certain inspection efforts to give their inspectors an opportunity to train with FDA personnel.

At the invitation of the Utah Board of Education, FDA co-sponsored a Midwinter Teachers Institute in Salt Lake City, January 28. Approximately 600 teachers attended the statewide meeting on health education.

DETROIT DISTRICT An "Indian princess" spieler was given a suspended sentence on a charge of making broad and unwarranted claims for three patent medicines. Chauncina White Horse, also known as Princess Yellow Rose, was sentenced at Fort Wayne, Ind., on December 22. The case developed from a doctor's complaint that Mrs. White Horse was promoting an herbal preparation for diabetes and one of his diabetic patients was taking the concoction instead of

insulin. She plead guilty to the charges.

Two workshops were co-sponsored with Michigan State University: "The Salmonella Problem in Non-Fat Dried Milk" on January 19, and "Salmonella in Frozen Eggs and Egg Products" on February 14.

In cooperation with the Indiana Health Department, the District conducted a workshop on "Salmonella in Non-Fat Dried Milk" on February 21. Another workshop, on "Good Manufacturing Practices for Drug Manufacturers," is planned at Purdue University on April 20.

KANSAS CITY DISTRICT More than 119,000 pounds of wheat containing a mercurial compound, shipped by Walsh Grain Co., Minneapolis, Minn., was seized at Wolcott & Lincoln, Inc., Kansas City, Kans. Some 130,000 pounds of similarly contaminated wheat, shipped by Frieling Grain Co., Gaylord, Kans., was also seized at Wolcott & Lincoln. Both shipments, valued at \$6,156, were destroyed in Kansas City on December 13.

The District had 3,297 cases of canned broccoli seized on December 21 because the broccoli was misbranded. The label showed whole broccoli heads, when the product actually consisted of irregularly sliced and chopped pieces. The broccoli, shipped by Stokley-Van Camp, Mount Vernon, Wash., was seized at Stokley-Van Camp, Kansas City, Kans., and was valued at \$7,250.

MINNEAPOLIS DISTRICT The entire State of Wisconsin has now been assigned to the jurisdiction of the District. Previously part of Wisconsin was in the Chicago District. The transfer will enable Wisconsin State officials to have a single channel of contact with one District office, and will equalize the workload between the two Districts.

NEW ORLEANS DISTRICT Two shipments, worth \$10,000, consisting of 1,600 cases of Portuguese canned tomato paste were detained. High mold content reflected use of unfit tomatoes.

Joint year-end inspections with the Mississippi State Board of Health and the Lincoln County Health Department revealed *Salmonella* contamination of non-fat dry milk in one plant. Over 300 50-pound bags, intended for use in ice cream, are being held for disposition at the direction of the Mississippi State Health Department. The joint investigations are continuing.

NEW YORK DISTRICT In the Nation's first jury trial dealing with the scope of the Government's right to inspect drug shipment records, the Government won.

Stanack Sales Co., Inc., Englewood, N. J., a wholesale drug firm, was convicted December 8, after it refused to allow FDA Inspectors to examine company records on the receipt and distribution of prescription drugs. Guilty verdicts were also returned against Howard Ackerman, secretary-treasurer, and his brother, Stanley, a salesman for the firm.

The Government charged that the defendants violated the 1962 Kefauver-Harris Drug Amendments. One aim of the amendments was to halt the flow of adulterated and misbranded drugs by inspecting records to find out the source and destination of shipments.

The defendants had argued that the Government did not show proof of FDA violations, necessary before FDA Inspectors could examine company records. The Government successfully argued that many prescription drugs at the firm were misbranded because they did not contain full disclosure information, and had incorrect addresses and misspelled generic names.

PHILADELPHIA DISTRICT An excess of metal particles in an eye ointment was revealed by District analysis. Winthrop Labs., Meyerstown, Pa., was inspected in early December, as a follow-up to Buffalo District's analysis of a routine sample of eye ointment. Inspectors found that the grid used by the firm to measure particle sizes in ointments contained a 10-fold error. The result was that metal particles were actually 10 times larger than those measured and recorded. The firm voluntarily recalled the batch from nationwide distribution.

The pre-Christmas "Flammable Doll" incident started with a call from the New Jersey Department of Health. The District cooperated with State and local officials taking action under their fire codes. The District also tested the dolls and judged them flammable under provisions of the Child Safety Act.

ST. LOUIS DISTRICT Due to misbranding, 18,700 pounds of Premium Calf Milk Replacer, valued at \$2,116, were seized December 14. The labeling contained false statements which represented that the product was adequate and effective for prevention of bacterial enteritis in calves. Manufactured and shipped

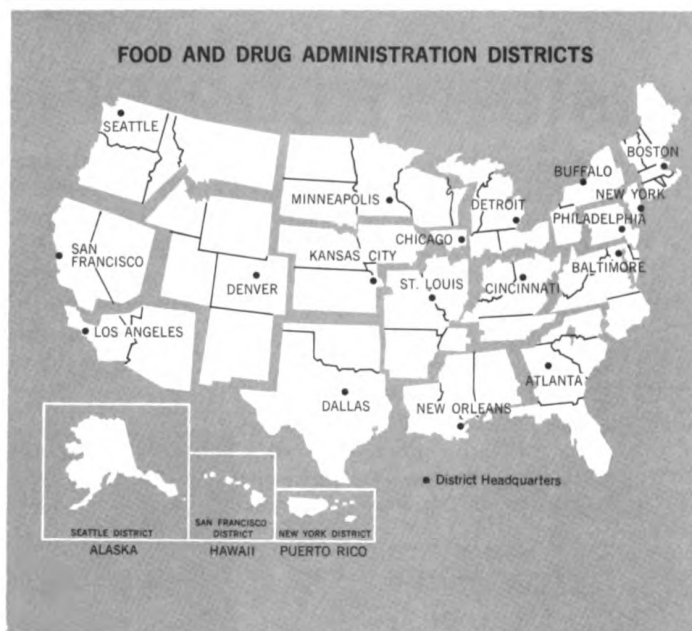
Imported doll ignites in 20 seconds in FDA test.



by Mutual Products Co., Minneapolis, Minn., the product was seized at Triple "A" Feed Co., Springfield, Mo.

SEATTLE DISTRICT The District and State agencies have been active in curtailing use of contaminated lots of seed screening for cattle feed. District examination of lots of alfalfa seed disclosed residues of toxaphene and DDT. Allied Seed Co., Pendleton, Oreg., voluntarily destroyed 40,000 pounds of the seed, and Beal Seed Co., Ontario, Oreg., destroyed 15,000 pounds. The Washington State Department of Agriculture also reported that during November their activities resulted in embargo of 28,901 pounds of contaminated seed.

To discuss problems of mutual concern, District laboratory and inspectional personnel and officials of the Washington State Department of Health and the Seattle-King County Health Department met in mid-December. The main topic was optimum use of facilities to control food-borne illness. The three groups offered to share facilities and information. The District is taking advantage of an offer by Seattle-King County to train personnel in epidemiological investigations. Due to excessive DDT residues, \$55,328 worth of Colby cheese imported from New Zealand was detained.



SAN FRANCISCO DISTRICT Inspection of Hawaiian Fruit Packers, Ltd., Kapaa, Hawaii, revealed that pineapple products were being canned under insanitary conditions. Heavy insect population was observed throughout the establishment. Thereafter official samples were collected on the mainland from shipments of canned pineapple tidbits, canned pineapple chunks, and canned, sliced pineapple. Over 1,200 cases, valued at \$8,000, were seized.

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 Bldg.
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

ST. LOUIS U.S. Courthouse & Customhouse
Bldg., Rm. 1002/1114 Market Street
St. Louis, Missouri 63101

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 02110

CHICAGO 205 West Wacker Drive
Engineering Building, Rm. 1700
Chicago, Illinois 60606

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

DENVER 1814 California Street
Denver, Colorado 80202

KANSAS CITY U.S. Courthouse
Rm. 803/811 Grand Avenue
Kansas City, Missouri 64106

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

NEW YORK 346 Broadway, 12th Floor
New York, New York 10013

state actions

Potato Products Destroyed A fire at Idaho Potato Growers, Idaho Falls, caused smoke and water damage to more than 360,000 pounds of prepared potato products. A city health sanitarian directed the segregation of damaged products for diversion to livestock feed.

box" radionic machines, used to diagnose and treat diseases ranging from cancer and heart trouble to kidney infections and head colds. Treatments allegedly could be transmitted through the air merely by placing a sample of the patient's blood in the machine.

achieving better feed control will be exchanged.

Current presiding officers are Mr. Van P. Entwistle, President, and Mr. Bruce Poundstone, Executive Secretary. Mr. Entwistle is director of feed control for the State of California. Mr. Poundstone is head of



Drown
therapeutic device
demonstrated by
FDA employee

'Diagnosticians' Convicted Two women have been convicted on grand theft charges associated with "radionic" treatments for serious diseases.

Cynthia Chatfield, D.C., and Mrs. Margaret Lunness, both of Los Angeles, Calif., were convicted in the state action on November 29 in Los Angeles. Their attorney has moved for a new trial.

Both women were associated with a laboratory founded by Dr. Chatfield's mother, the late Ruth Drown, D.C. Dr. Drown was originally indicted in 1963 with the other two women. She died in 1965 at age 74.

Involved in the case were "black

In 1951 Dr. Drown was convicted, under the Food, Drug, and Cosmetic Act, of misbranding the device. This case involved a Chicago woman who died of cancer while taking the Drown treatment.

Annual Seminar The Association of American Feed Control Officials will hold their Second Annual Seminar on Administration and Management of Feed Laws, on March 12-17, 1967.

This meeting, to be held at the University of Kentucky at Lexington, will be devoted to considerations of uniformity in legislation and enforcement policies. In addition, views and procedures for

Regulatory Services Division of the University of Kentucky.

New State Appointments Among the recent appointments to State food and drug posts are: Mr. Walter C. Leth, Director, State Department of Agriculture, Oreg.; Mr. James L. Casey, Commissioner, State Department of Consumer Protection, Conn.; Dr. Walter B. Quisenberry, Director of Health, Hawaii; Mr. Earl Coke, Director, State Department of Agriculture, Calif.; Mr. Richard Beard, Commissioner, State Department of Agriculture and Industries, Ala.; Mr. James Ballinger, President, State Board of Agriculture, Okla.; and Mr. L. B. Liddy, Secretary, State Department of Agriculture, Iowa.

seizures and proceedings

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 76 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market were reported in December. These included 54 seizures of foods; 3 because of poisonous and deleterious substances, 40

because of contamination, and 11 because of economic violations. Other seizures included 12 of human drugs, 2 of veterinary drugs, 5 of medical devices, 2 of prophylactics, and 1 of a hazardous substance.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Poisonous and Deleterious Substances		
Horseradish, dehydr./Fort Polk, La. 12/8/66	Allen Foods, Inc./St. Louis, Mo. (S)	Contains sharp particles of silica gel and insects.
Lettuce, fresh/Forty Fort, Pa. 11/17/66	J. R. Norton Co./Phoenix, Ariz. (P,S)	Contains toxaphene, a pesticide chemical not in conformity with regulations.
Kearney, N.J. 11/15/66	Western Growers Distributing Co./Glendale, Ariz. (P,S)	Contains toxaphene and parathion, exceeding established tolerance for pesticide chemicals.
Contamination, Spoilage, Insanitary Handling		
Anchovies, can./Pittsburgh, Pa. 12/5/66	Don Juan Foods, Inc./Brooklyn, N.Y. (S)	Partly decomposed.
Butter/St. Paul, Minn. 11/10/66	Western Dairy Co./Clarkfield, Minn. (M,S)	Prepared and packed under insanitary conditions; insect contaminated.
Candy and Gum/Waco, Tex. 12/14/66	Harry Siegel Food Distr., Inc./Waco, Tex. (D)	Held under insanitary conditions.
Corn Husks/Phoenix, Ariz. 11/25/66	California Corn Husk Co./Norwalk, Calif. (S)	Insect-damaged and moldy corn husks.
Cumin Seed, Garbanzos, Garlic/San Juan, P.R. 12/7/66	Mendez & Co., Inc./San Juan, P.R. (D)	Insect and rodent contaminated.
Eggs, frozen/Warminster, Pa. 12/2/66	Nulaid Foods/San Leandro, Calif. (S)	Partly decomposed.
Brooklyn, N.Y. 12/14/66	"	"
San Leandro, Calif. 12/20/66	"	"
Thomasville, Ga. 11/21/66	Pacific Growers/San Leandro, Calif. (S)	"
Kansas City, Kans. 12/21/66	"	"
Flour/Mayaguez, P.R. 11/23/66	Arbona Hermanos/Mayaguez, P.R. (D)	Held under insanitary conditions.
Spruce Pine, N.C. 12/2/66	Spruce Pine Wholesale Co./Spruce Pine, N.C. (D)	"
Harahan, La. 12/13/66	Food Suppliers, Inc./Harahan, La. (D)	"
Columbia, S.C. 12/13/66	Rawl Dist. Co./Columbia, S.C. (D)	"
Flour, Rice, etc./Lancaster, S.C. 10/25/66	Plyer Wholesale Co., Inc./Lancaster, S.C. (D)	"
Macaroni, Rice, etc./Lenoir, N.C. 12/2/66	City Flour & Feed Co., Inc./Lenoir, N.C. (D)	"
Meat Casings/Detroit, Mich. 11/18/66	Butcher & Packer Supply Co./Detroit, Mich. (D)	Held under insanitary conditions; insect contaminated.
Peanuts, shelled/Olympia, Wash. 12/5/66	Matthews Candy Co./Olympia, Wash. (D)	Held under insanitary conditions; rodent contaminated.
Los Angeles, Calif. 12/1/66	Gust Picoulas & Co./Los Angeles, Calif. (D)	"
Peas (Garbanzos)/Santurce, P.R. 12/1/66	Puerto Rico Warehouse Corp./Santurce, P.R. (D)	Insect contaminated.
Blackeye, can./St. Louis, Mo. 12/15/66	F. M. Weiling & Son Whse./Kansas City, Mo. (S)	Partly decomposed.
Pecans, shelled/New Orleans, La. 12/8/66	Williams Pecan Products Co./Gulfport, Miss. (P,S)	Prepared and packed under insanitary conditions.
" " " 12/13/66	"	"
Peppermint Candy/Mount Holly Springs, Pa. 12/16/66	Earl's Candy Co./Macon, Ga. (M,S)	"
Rosenberg, Tex. 12/16/66	"	"
Perch/Gloucester, Mass. 12/9/66	Twin Light Fillet, Inc./Gloucester, Mass. (P,S)	Contaminated by parasitic copepods.
Pineapple, can./Orville, Calif. 11/18/66	Hawaiian Fruit Packers, Ltd./Kapaa, Hawaii (P,S)	Prepared and packed under insanitary conditions.
Alameda, Calif. 12/22/66	"	"
Prunes, froz./Chicago, Ill. 12/2/66	The Phillips Co./Chicago, Ill. (D)	Moldy.
Shrimp, froz./Washington, D.C. 11/30/66	Singleton Packing Corp./Tampa, Fla. (P,S)	Prepared and packed under insanitary conditions; E. coli, staphylococci.
Denver, Colo. 12/2/66	Booth Fisheries/Brownsville, Tex. (P,S)	"
Des Moines, Iowa 11/14/66	"	"
Walterboro, S.C. 11/16/66	Singleton Packing Corp./Tampa, Fla. (P,S)	"
Shrimp, froz., stuffed/N. Miami, Fla. 11/14/66	Sea Pak Corp./St. Simons Island, Ga. (P,S)	"
breaded/Detroit, Mich. 11/30/66	Singleton Packing Corp./Tampa, Fla. (P,S)	"

seizure actions

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Contamination, Spoilage, Insanitary Handling (cont'd)		
Shrimp, breaded Denver, Colo. 12/20/66	Sea Pak Corp./St. Simons Island, Ga. (P,S)	Prepared and packed under insanitary conditions; E. coli, staphylococci.
Soup Mix/Miami, Fla. 8/25/66	Hi-Grade Food Co., Inc./Miami, Fla. (D)	Held under insanitary conditions; insect contaminated.
Spinach, can./Iola, Kans. 11/21/66	Model Wholesale Grocery Co./Iola, Kans. (D)	Decomposed.
Strawberries and Blueberries/Chicago, Ill. 12/2/66	The Phillips Co./Chicago, Ill. (D)	"
Tomato Paste, can./Roxbury, Mass. 12/5/66	Buy-Rite Co., Inc./Roxbury, Mass. (D)	"
Economic Violations		
Butter/Chicago, Ill. 12/21/66	A. Suchy Co./Chicago, Ill. (D)	Contains less than 80 percent of butterfat.
Candy Pecanettes/Fairless Hills, Pa. 12/2/66	Hillside Enterprises, Inc./Cleveland, Ohio (S)	Short weight.
Jellies, asst./Cleveland, Ohio 12/14/66	Utt Juice Co./Tustin, Calif. (S)	Inaccurate quantity of content statement.
Mango Juice, reconstit./Vernon, Calif. 8/24/66	Dolphin Int. Trading Co./Houston, Tex. (S)	False and misleading claims to calm the stomach, promote health, and be of special dietary use.
Oleomargarine/Vestal, N.Y. 11/28/66	Old Dutch Foods, Inc./Vestal, N.Y. (D)	Fails to conform to margarine standards; below required butterfat content.
Orange Juice/Goldsboro, N.C. 11/25/66	Coble Dairy Products, Coop., Inc./Anderson, S.C. (M,S)	Other substances substituted in part for orange juice; fails to conform to orange juice standards.
Athens, Ga. 11/23/66	"	"
Shrimp, can./Phoenix, Ariz. 12/7/66	Safeway Stores, Inc./E. Stockton, Calif. (S)	Misleading vignette depicting whole shrimp, broken pieces substituted.
Shrimp, froz./Salt Lake City, Utah 12/22/66	Rose Frozen Shrimp/Los Angeles, Calif. (P,S)	Fails to conform to standard and definition for shrimp.
Tomatoes, can./Iola, Kans. 11/21/66	Allen Canning Co./Siloam Springs, Ark. (S)	Below quality standard for canned tomatoes.
Martinsville, Va. 12/16/66	A. W. Sisk & Son/Cambridge, Md. (S)	"
DRUGS / Human Use		
Afrodex capsules/Houston, Tex. 11/16/66	Bentex Pharmaceuticals Co./Houston, Tex. (D)	Inadequate directions for use.
Allergimist "Solution A" and "Solution B" Rosemead, Calif. 11/16/66	The Brunson Corp./Miami, Fla. (M,S)	New drug not approved for safety and effectiveness.
Van Nuys, Calif. 11/16/66 (2 actions)	"	"
Gardena, Calif. 11/16 and 11/21/66	"	"
Los Angeles, Calif. 11/16/66	"	"
Vernon, Calif. 11/21/66	"	"
San Bernardino, Calif. 11/22/66	"	"
Baker's Hair Tonic/Oklahoma City, Okla. 12/20/66	Hal Collins Co./Dallas, Tex. (M,S)	Inconspicuous and insufficient mandatory labeling information.
Diazym caps, GH-4 Digestant caps., Multi-Vit. No. 465/Los Angeles, Calif. 11/18/66	W. H. Crew Mfg. Co./Salt Lake City, Utah (M,S)	Contains poisonous Salmonella micro-organisms.
Erosol (bath lotion)/New York, N.Y. 11/23/66	Erosol, Inc./New York, N.Y. (D)	False and misleading claims to increase blood circulation, achieve complete satisfaction in marital relations, be ideal as a vaginal lubricant.
Go-Pain Ointment/Dallas, Tex. 10/18/66	De Pree Co./Holland, Mich. (M,S)	False and misleading claims to relieve muscular aches, sprains, neuralgia, lumbago, chest colds.
Thyroid Powder/Auburn, Mass. 12/19/66	Elasto Chemical Corp./New York, N.Y. (M,S)	Below U.S.P. quality standard.
Veterinary		
Electro Dex, Chloro-Histex, Chloro-Lac, Amino-Com 10/Billings, Mont. 7/8/66	Lyle A. Wittney & Co./Denver, Colo. (M,S)	New drugs not approved for safety and effectiveness; below labeled quality; inadequate directions for use.
Phenothiazine/Chicago, Ill. 12/2/66	William Cooper & Nephews, Inc./Pittsburgh, Pa. (D)	False and misleading claims to remove ascarid worms from hogs; inadequate directions for use.
MEDICAL DEVICES		
Catheterization Set/Evanston, Ill. 10/24/66	Pharmaseal Laboratories/Irwindale, Calif. and/or Johnson City, Tenn. (M,S)	Below labeled quality, not "sterile."
Contour Control/Jackson, Miss. 12/15/66	Nemeth & Hammond Enterprises/Dallas, Tex. (M,S)	False and misleading claims for reducing.
Figure Control/Minneapolis, Minn. 11/23/66	Consumer Electronics/Dallas, Tex. (M,S) and Hydro Massage, Inc./Minneapolis, Minn. (D)	False and misleading claims for reducing, increasing flow of blood, getting rid of wrinkles; inadequate directions for use.
Hygienic Tooth Brush/St. Louis, Mo. 12/15/66	Sterling Merchandise Co., Inc./New York, N.Y. (S)	False and misleading claims of superior quality, bristles not securely fastened.
Nord-Craft Finn-ette Sauna/Madison, Wis. 12/22/66	Heritage Sauna Co./Minneapolis, Minn. (S)	False and misleading claims to relax taut nerves, ease tension, maintain excellent health.

seizure actions

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Prophylactics		
Rubber/Dallas, Tex. 10/19/66 Knoxville, Tenn. 12/8/66	Allied Latex Sales Co., Inc./Dothan, Ala. (S) National Hygienic Prod. Corp./Dothan, Ala. (S)	Defective. "
HAZARDOUS SUBSTANCES		
Crete Hardener, Titan Catalyst "P"/ Seattle, Wash. 12/5/66	Sarfan Corp./San Francisco, Calif. (P,S)	Lacks consumer protection information required by the, Fed'l. Hazardous Substances Act.

TERMINATED CRIMINAL CASES

charging violation of the Federal Food, Drug, and Cosmetic Act are published when the court action has been reported by the FDA District office.

DEFENDANT	PRODUCT, PRINCIPAL VIOLATION CHARGED, SENTENCE & JURISDICTION	DEFENDANT	PRODUCT, PRINCIPAL VIOLATION CHARGED, SENTENCE & JURISDICTION
UNFIT FOOD		MISBRANDED FEED	
Sherwood Candy Co., and Albert J. Plunkett Atlanta, Ga. G. Santoro & Sons, Inc. Joseph Signorelli Brooklyn, N.Y.	Peanuts and corn sirup held under insanitary conditions. Company and individual each fined \$200. (N. Dist. of Ga.-Atlanta) Macaroni products prepared and packed under insanitary conditions. Corporation fined \$8,000; individual placed on 18-month probation. (E. Dist. of N.Y.-Brooklyn)	Security Mills, Inc., and Charles P. Crawford Knoxville, Tenn.	Shipping of adulterated and misbranded medicated feed. Fined \$2,000. (E. Dist. of Tenn.-Knoxville)
ILLEGAL SALES OF PRESCRIPTION DRUGS			
Georgia-Mableton Drug Corp., t/a Liggett-Rexall Drugs, and Joe A. Ballew Eddie Frank Daniel Mableton, Ga. Albert H. Pollack (pharmacist) Chicago, Ill.	Unauthorized refilling of amphetamine and tranquilizer prescriptions. Corporation fined \$200; Ballew and Daniel, each \$100. (N. Dist. of Ga.-Atlanta) Selling amphetamine and phenylbutazone without prescription. Fined \$250 and \$28 costs; placed on 3-year probation. (N. Dist. of Ill.-Chicago) Selling amphetamine and cortisone without prescription. Fined \$350, plus \$15 costs. (N. Dist. of Ill.-Chicago) Selling antibiotic and tranquilizer without prescription. Blume fined \$300, plus \$41 costs; Andrews, \$100. (N. Dist. of Ind.-South Bend) Selling amphetamine outside doctor-patient relationship. Fined \$3,000, plus \$76.88 costs; placed on 4-year probation. (N. Dist. of Iowa-Fort Dodge)	Jimmy W. Mitchell Hamilton, Ohio Oscar H. Locke, t/a 60 Grand Truck Stop, and Donald Hughes Virgil L. Brown Joe Curtis Junior Hoover Wyandotte, Okla. George Lee Dallas, Tex.	Peddling amphetamine. Sentenced to 1 year in jail. (E. Dist. of Ky.-London) Peddling amphetamine. Locke fined \$500; placed on 2-year probation; co-defendants not sentenced. (N. Dist. of Okla.-Tulsa)
David S. Macklin, mgr. Eastgate Drugs, Inc. Lombard, Ill. Harold S. Blume, t/a Blume Pharmacy, and Wayne A. Andrews South Bend, Ind. Bahne K. Bahnsen, D.O. Burt, Iowa	Selling amphetamine and cortisone without prescription. Fined \$350, plus \$15 costs. (N. Dist. of Ill.-Chicago) Selling antibiotic and tranquilizer without prescription. Blume fined \$300, plus \$41 costs; Andrews, \$100. (N. Dist. of Ind.-South Bend) Selling amphetamine outside doctor-patient relationship. Fined \$3,000, plus \$76.88 costs; placed on 4-year probation. (N. Dist. of Iowa-Fort Dodge)	Booker T. Metcalf (employee Texas T.S.) Dallas, Tex. Frost Drug Co., and Eldon L. Frost, pres. Gerald K. Okabe, pharm. Kaysville, Utah Dwight M. Hoke, M.D. Beckley, W. Va.	Peddling amphetamine. Sentenced to 2 years in jail, suspended, and placed on 2-year probation. (N. Dist. of Tex.-Dallas) Peddling amphetamine. Sentenced to 6 months in jail, suspended, and placed on 2-year probation. (N. Dist. of Tex.-Dallas) Unauthorized refilling of prescription drugs. Company fined \$800; Frost, \$400, \$200 suspended; Okabe, \$1,200, suspended. (N. Dist. of Utah-Ogden) Selling amphetamine and barbiturates outside doctor-patient relationship. Fined \$1,000; placed on 1-year probation. (S. Dist. of W. Va.-Charleston)
James Leo Lanham Covington, Ky. Augustus D. Slone, M.D. Paintsville, Ky.	Peddling amphetamine. Sentenced to 4 months in jail. (E. Dist. of Ky.-London) Selling antibiotic, cortisone, and tranquilizers outside doctor-patient relationship. Fined \$600, plus \$35 costs. (E. Dist. of Ky.-Pikeville)	Goff P. Lilly, M.D. Charleston, W. Va.	Selling amphetamine, penicillin, Enovid, and Norlestrin outside doctor-patient relationship. Fined \$1,000; placed on 1-year probation. (S. Dist. of W. Va.-Charleston)
Harry Zarafonettis Springhill, La.	Peddling amphetamine and barbiturates. Sentenced to 2 years in jail, 1 additional year, suspended, and placed on 3-year probation. (W. Dist. of Ark.-Eldorado)	MISBRANDED AND NEW DRUGS	
John K. Newton Minneapolis, Minn.	Illegal sales of amphetamine. Fined \$500; placed on 3-year probation. (Dist. of Minn.-Minneapolis)	Chauncina White Horse, t/a Princess Yellow Rose Shipshewana, Ind.	Misbranding ointments orally with false and misleading claims. Sentence suspended; no probation imposed. (N. Dist. of Ind.-Fort Wayne)
Jimmy Lee Buckner Weaverville, N.C.	Peddling amphetamine. Sentenced to 1 year in jail, suspended, placed on 3-year probation, and fined \$500. (W. Dist. of N.C.-Asheville)	Floyd S. Foreman, t/a Darigon Corp. Knoxville, Tenn.	Misbranding amphetamine, not manufactured in a duly registered establishment, and without adequate directions for use. Sentenced to 1 year in jail. (E. Dist. of Tenn.-Knoxville)
Joseph Ford Hodge Wilkesboro, N.C.	Peddling amphetamine. Sentenced to 2 weeks in jail, placed on 5-year probation, and fined \$500. (M. Dist. of N.C.-Wilkesboro)	The Pharmadent Co., and Erwin J. Franke, Jr. Lake Jackson, Tex.	Shipping of Prednisolone Desensitizing Solution, a new drug without an effective new-drug application. Company fined \$1,500; individual, \$250. (S. Dist. of Tex.-Houston)
Tom Allen Coalson (t/a Coalson's Drive-in) Winston-Salem, N.C.	Peddling amphetamine. Sentenced to 1 year in jail, and fined \$1,000. (M. Dist. of N.C.-Winston-Salem)		

**NOTICES OF JUDGMENT on Seizure Actions
FOOD / Poisonous and Deleterious Substances**

Celery, fresh, Season's Best, at Cleveland, N. Dist. Ohio.
Charged 2-2-66: when shipped by Season Produce Co., Inc., Los Angeles, Calif., the article contained a quantity of the added pesticide chemical toxaphene in excess of the tolerance; 402(a)(2)(B). Default decree ordered destruction. (1)

Wheat Shirts, at West Plains, W. Dist. Mo.
Charged 7-1-66: when shipped by Moore-Lowry Flour Mills, Inc., Coffeerville, Kans., the article contained the food additive DDT, and it and its use and intended use failed to conform to regulation or exemption; 402(a)(2)(C), 409. Default decree ordered destruction. (2)

FOOD / Contamination, Spoilage, Insanitary Handling

Eggs, frozen, at Chicago, N. Dist. Ill.
Charged 12-16-65: when shipped by Schneider Bros., Inc., Birmingham, Ala., and J. K. Brokerage, Boaz, Ala., two lots of eggs contained decomposed eggs; 402(a)(3). Consent decree authorized release of the lot of eggs in labeled cans to Schneider Bros., Inc., for salvaging. Default decree ordered destruction of the lot of eggs in unlabeled cans. (3)

Chickens, ready to cook, Sunny Boy, at Mankato, Dist. Minn.
Charged 6-24-65: when shipped by Braman Poultry, Inc., Cleveland, Ohio, poultry, not ready to cook, containing hair, feathers, oil and sex glands, vents, lung, esophagus, and intestinal tissue, and dirt had been substituted for the article; and the article bore false and misleading statements about its being ready to cook and its inspection by U. S. Dept. of Agriculture; 402(b)(2), 403(a). Consent decree authorized release to shipper for reprocessing, but shipper failed to comply and the article was ordered destroyed. (4)

Potato product, frozen, "Tater-Buds", at Milton, Mass.
Charged 7-19-65: when shipped by Vahlsing, Inc., Easton, Maine, the article contained E. coli, and other bacterial filth, 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. (5)

Potato starch, at Houston, S. Dist. Tex.
Charged 6-8-66: while held by Houston City Dock Warehouse, Houston, Tex., the article contained insect filth and nondescript dirt, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (6)

Beans, red, Azuki, at Los Angeles, S. Dist. Calif.
Charged 1-14-66: while held by Maruya 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. (7)

Beans, pinto, dried, and peas, split, green, at Stockton, N. Dist. Calif.
Charged 3-1-66: while held by Port Stockton Food Distributors, Inc., Stockton, Calif., the articles contained rodent filth, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (8)

Oleomargarine, at Hendersonville, W. Dist. N.C.
Charged 6-13-66: when shipped by Shedd-Bartush Foods, Inc., Greenville, S.C., the article had been prepared, packed, and held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (9)

Cocoa, at Chicago, N. Dist. Ill.
Charged 8-4-65: while held for sale by Bakers Specialty Co., Chicago, Ill., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Bakers Specialty Co. for salvaging. (10)

Tomato juice, canned, Hunt's, at Rossford, N. Dist. Ohio.
Charged 3-2-66: when shipped by Hunt Foods & Industries, Inc., Rossford, Ohio, the article contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (11)

Tomato juice, canned, Del Monte Brand, at Frankfort, S. Dist. Ind.
Charged 3-21-66: when returned to the shipper, California Packing Corp., Frankfort, Ind., the article labeled "Del Monte Brand Quality Tomato Juice" distributed by California Packing Corporation, San Francisco, California, contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (12)

Tomato puree, canned, Gateway Brand, at St. Paul, Dist. Minn.
Charged 1-27-66: when shipped by Perry Canning Co., Perry, Utah, the article contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (13)

Tomato paste, canned, at Toledo, N. Dist. Ohio.
Charged 11-16-65: when returned to the original shipper, Hirzel Canning Co., Toledo, Ohio, the article contained a decomposed substance; 402(a)(3). Default decree ordered destruction. (14)

Tomatoes and tomato juice, canned, Biffy Brand, at Richmond, E. Dist. Ky.
Charged 1-27-66: when shipped by Kenneth N. Rider Co., Inc., Trafalgar, Ind., the articles contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (15)

Nuts, mixed, Martin's Finest, at Bedford, N. Dist. Ohio.
Charged 1-17-66: when shipped by B & S Produce Co., Detroit, Mich., the article contained [insect] filth, and moldy, rancid, decomposed and shriveled nuts; 402(a)(3). Default decree ordered destruction. (16)

Filberts and brazil nuts, shelled, at Norfolk, E. Dist. Va.
Charged on or about 12-7-65: when shipped by Peanut Products Co., Des Moines, Iowa, the articles contained insect filth and moldy, rancid, and decomposed nuts; 402(a)(3). Default decree ordered destruction. (17)

Nuts, mixed, unshelled, at Atlanta, N. Dist. Ga.
Charged 11-26-65: while held for sale, the article contained rancid, decomposed, shriveled and gummy nuts, and empty shells; 402(a)(3). Default decree ordered destruction. (18)

Nuts, mixed, unshelled, at Landover, Dist. Md.
Charged 12-14-65: while held for sale, the article contained insect filth, and rancid, moldy, gummy, and shriveled nuts, and empty shells; 402(a)(3). Consent decree authorized release to Graham Co., Inc., New York, N. Y., for salvaging. (19)

Pecans, shelled, Fiesta Brand, at Jackson, E. Dist. Mich.
Charged 2-25-66: when shipped by D. McCrea & Son, Inc., Yancey, Tex., the article contained E. coli, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (20)

Chestnuts, at Norfolk, E. Dist. Va.
Charged 12-3-65: while held for sale, the article contained insect filth,

and moldy, decomposed chestnuts; 402(a)(3). Default decree ordered destruction. (21)

Chestnuts, at Halethorpe, Dist. Md.
Charged 1-10-66: when shipped by Squillante, New York, N. Y., the article contained insect filth, and moldy, decomposed nuts; 402(a)(3). Default decree ordered destruction. (22)

Chestnuts, at Philadelphia, E. Dist. Pa.
Charged 12-13-65: when shipped by Cuneo Bros., Inc., New York, N. Y., the article contained decomposed chestnuts; 402(a)(3). Default decree ordered destruction. (23)

Pecans, shelled, Fiesta Brand, at Denver, Dist. Colo.
Charged 2-25-66: when shipped by D. McCrea & Son, Inc., Yancey, Tex., the article contained E. coli, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (24)

Pecans, unshelled, at Nashville, M. Dist. Tenn.
Charged 12-7-65: when shipped by Grizzard Bros., Forest Park, Ga., the article contained insect filth, and moldy, decomposed, and shriveled nuts, and empty shells; 402(a)(3). Default decree ordered destruction. (25)

Pecans, shelled, at Sioux Falls, Dist. S. Dak.
Charged 3-10-66: when shipped by Texas Nut Co., Dallas, Tex., the article contained E. coli and other bacterial filth; 402(a)(3). Default decree ordered destruction. (26)

Peanuts, at Buffalo, W. Dist. N.Y.
Charged 5-31-66: when shipped by Dixie Peanut Co., Fitzgerald, Ga., the article contained insect filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the shipper for salvaging. (27)

Flour and mixed nuts, at Xenia, S. Dist. Ohio.
Charged 3-24-66: while held by Super Valu Stores, Inc., Xenia, Ohio, the articles contained rodent filth, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (28)

Flour, at Jackson, E. Dist. Ky.
Charged 2-7-66 and amended 5-9-66: while held by Jackson Wholesale Co., Jackson, Ky., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized destruction. (29)

Flour, at Canton, N. Dist. Ga.
Charged 9-19-66: while held by Canton Wholesale Co., Canton, Ga., the article contained rodent and insect filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (30)

Flour, at Springfield, Dist. Mass.
Charged 4-15-66: while held by Magaziner's Bakery Co., Inc., Springfield, Mass., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction, or donation to public/charitable institution for use as animal feed. (31)

Candy, rice, and flour, at South Hill, E. Dist. Va.
Charged 11-9-65: while held by South Hill Grocery Co., Inc., South Hill, Va., the articles contained insect filth, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree authorized donation to public/charitable institution for use as animal feed. (32)

FOOD / Economic Violations

Pickles, at New York, S. Dist. N. Y.
Charged 1-4-66: when shipped by Wholesale Society of German Consumers Cooperative Societies, Hamburg, West Germany, the article was short weight (approx. 8.7 percent); 402(e)(2). Consent decree authorized release to Harn-Christensen & Co., Inc., New York, N. Y., for relabeling. (33)

Nuts, mixed, salted, Big Valu, at Fargo, Dist. N. Dak.
Charged 11-5-65: when shipped by Super Valu Stores, Inc., Hopkins, Minn., the article labeled "Big Valu Salted Mixed Nuts" distributed by Select Products bore a false and misleading label vignette, since the vignette depicted mostly nuts other than peanuts and the article was mostly peanuts, (approx. 88 percent); and the label failed to state that the article contained chemical preservatives; 402(a), 403(k). Default decree authorized donation to public/charitable institution. (34)

Mackerel, canned, Tip-Apa Brand, at Fajardo and Camuy, Dist. P. R.
Charged 6-26-64: when shipped by Van Camp Sea Food Co. (a division of Ralston Purina Corp.), Terminal Island, Calif., jack mackerel had been substituted for the article, and the label was false and misleading, since Jack mackerel is not mackerel (or California mackerel) and does not belong to the true mackerel family Scombridae; 402(b)(2), 402(a). Consent decree authorized release to shipper for relabeling. (35)

Lemon juice, reconstituted, Two Guys, 2 seizure actions at Garfield, Dist. N. J.
Charged 9-28-65 and on or about 10-21-65: when shipped by Arthur Mitchell Food Products, Inc., Brooklyn, N. Y., the article labeled "Two Guys Reconstituted Lemon Juice" distributed by Two Guys, Inc., Garfield, N.J., had had a valuable constituent omitted, a substance other than reconstituted lemon juice had been substituted for the article, and the label was false and misleading, since the article was a mixture of reconstituted lemon juice and a different substance; 402(b)(1), 402(b)(2), 403(a). Default decree authorized donation to public/charitable institution. (36)

Tomato puree, canned, Candid Brand, at Hamilton, S. Dist. Ohio.
Charged 11-18-65: when shipped by Eaton Foods, Inc., Eaton, Ind., the article was short weight (approx. 2.74 percent); 403(e)(2). Default decree authorized donation to public/charitable institution. (37)

Cranberry juice cocktail, Clever Farm Brand, at Nashua, Dist. N. H.
Charged 12-22-64: when shipped by New England Apple Products Co., Inc., Littleton, Mass., the article was made to appear better and of greater value than it was; and its label lacked the name of each ingredient, and failed to declare artificial coloring, since the article contained an unstated artificial red coloring; 402(b)(4), 403(i)(2), 403(k). Consent decree authorized donation to public/charitable institution. (38)

Shrimp, breaded, fantail, frozen, Albuquerque, Dist. N. Mex.
Charged 4-1-66: when shipped by Rose Frozen Shrimp, Inc., Los Angeles, Calif., the article tested less than 50 percent shrimp material; 403(e)(1). Consent decree ordered destruction. (39)

Sausage seasoning, Keepsweet, at Kansas City, W. Dist. Mo.
Charged 3-23-66: when shipped by Madison Labs., Chicago, Ill., the label did not declare the ingredient ascorbic acid, and failed to state

that a chemical preservative had been added; 403(i)(2), 403(h). Default decree authorized donation to public/charitable institution. (40)

FOOD ADDITIVES

Ethoxyquin premix, at Charlotte, W. Dist. N.C.

Charged 12-9-65: when shipped by Peter Hand Foundation, Chicago, Ill., the article contained the food additive ethoxyquin, and its use and intended use failed to conform to regulations, since the article failed to bear adequate directions for use; 402(a)(2)(C), 409. Consent decree authorized release to shipper for relabeling. (41)

VITAMINS / DIETARY FOOD

Dietary Feed Supplement tablets and powders, at Old Saybrook, Dist. Conn.

Charged 2-24-65: while held for sale, valuable constituents had been omitted or abstracted from the articles, and the label statements were false and misleading since the tablets were deficient in vitamin A (approx. 50 percent) and the powders were deficient in vitamins C and A (approx. 90 percent and 60 percent, respectively); 402(b)(1), 403(a). Default decree ordered destruction. (42)

Dietary supplemental tablets, at Pownal, Dist. Vt.

Charged 11-9-64: while held for sale, a valuable constituent had been omitted or abstracted from the article, and the label was false and misleading since the article was deficient in vitamin A (approx. 40 percent); 402(b)(1), 403(a). Default decree ordered destruction. (43)

Food Supplement Capsules, NeoLife, at Oakland, N. Dist. Calif.

Charged 4-8-64: when returned to its original shipper, Neo-Life Co. of America, Oakland, Calif., the article contained the food additive folic acid, and it and its use and intended use failed to conform to regulation or exemption; 402(a)(2)(C), 409. Default decree ordered destruction. (44)

ANIMAL FEEDS

Poultry premix, special, at Lexington, E. Dist. Ky.

Charged 2-11-66: when shipped by Philips Roxane Div., Thompson-Hayward Chemical Co., subsidiary of Philips Electronics, Kansas City, Mo., a valuable constituent had been omitted, and the label was false and misleading since the article was deficient in vitamin D (approx. 90 percent); 402(b)(1), 403(a). Default decree ordered destruction or release to public/charitable institution for use as animal feed. (45)

Poultry feed, medicated, Q-B Plus Starter, at Kansas City, W. Dist. Mo.

Charged 4-13-65: while held by Gilsenberry Mills, Inc., Kansas City, Mo., the article had been prepared from the food additive nihydrozone, which had been shipped in interstate commerce, and it and its use and intended use failed to conform to regulation or exemption; the strength of the article was deficient; and the label false and misleading since the article was deficient in nihydrozone (approx. 50 percent) (see D.D.N.J. No. 8650); 402(a)(2)(C), 409, 501(c), 502(a). Default decree authorized donation to public/charitable institution for use as animal feed. (46)

Poultry feed, medicated, Arizona Star, at Phoenix, Dist. Ariz.

Charged 1-21-65: while held by Arizona Milling Co., Phoenix, Ariz., the articles had been prepared from the food additive nihydrozone, which had been shipped in interstate commerce, and it and its use and intended use failed to conform to regulation or exemption, since its labeling failed to declare nihydrozone and it lacked other required statements; and the label was false and misleading in claiming the article contained nitrofurazone and furazolidone (see D.D.N.J. No. 8620); 402(a)(2)(C), 409, 502(a). Default decree ordered destruction. (47)

Stock Feed Tonic, U. S., at Atlanta, S. Dist. Ind.

Charged 2-23-65: when shipped by the United States Food Co., Pleasant City, Ohio, the article contained the food additive American Wormseed, and it and its intended use failed to conform to regulation or exemption, since the article was intended for continuous free-choice feeding to cattle, sheep, and young pigs; 402(a)(2)(C), 409. Default decree ordered destruction. (48)

Feed, medicated, Pre-Wear-R-Jets, at Redwood Falls, Dist. Minn.

Charged 3-2-66: when shipped by Doughboy Industries, Inc., New Richmond, Wis., the article was deficient and its labeling was false and misleading, since the article was deficient in sulfamethazine (approx. 25 percent) and lacked exemption from antibiotic certification; 501(c), 502(a), 502(i). Default decree ordered destruction. (49)

Medicated feed, at Louisville, W. Dist. Ky.

Charged 3-30-65, amended on or about 7-27-65: while held by Henry Fruechteicht Co., Inc., Louisville, Ky., the strength of the article, which had been manufactured locally by the dealer from an arsenic acid premix shipped in interstate commerce, was deficient and its labeling was false and misleading as to amount and efficacy, since the article was deficient in diethylstilbestrol; 501(c), 502(a). Consent decree ordered destruction. (50)

Medicated feed, Dakota Maid, at Grand Forks, Dist. N. Dak.

Charged 3-23-66: while held by North Dakota Mill & Elevator Co., Grand Forks, N. Dak., the strength of the article, which had been manufactured locally by the dealer from diethylstilbestrol shipped in interstate commerce, was deficient and its labeling was false and misleading as to amount and efficacy, since the article was deficient in diethylstilbestrol; 501(c), 502(a). Default decree authorized donation to public/charitable institution for use as animal feed. (51)

DRUGS / Human Use

Lazexes, Bio-Laz, at West Hazelton, M. Dist. Pa.

Charged 1-27-66: when shipped by Schlicksup Drug Co., Inc., Peoria, Ill., the strength of the article was deficient and the labeling false and misleading, since the article was deficient in tyrothricin and benzocaine and the article lacked an antibiotic certificate or release; 501(c), 502(a), 502(i). Default decree ordered destruction. (52)

Pituitary tablets, at Pasadena, S. Dist. Calif.

Charged 6-11-65: while held for sale, the labeling of the article labeled "Tablets pituitary" . . . Nelson-Boyer Company . . . Glendale, Calif. . . Oral dose . . . which had been manufactured locally from pituitary shipped in interstate commerce, lacked adequate directions for use and was not exempt from such requirement; 502(f)(1). Default decree ordered destruction. (53)

Amphetamine drugs, various, at Lewisville, S. Dist. Ind.

Charged on or about 9-8-64: while held by Marion R. Scheetz, M.D., the labeling lacked adequate directions for use and the articles were not exempt as prescription drugs, since they were not for use or dispensing in professional practice; 502(f)(1). Default decree ordered destruction. (54)

Amphetamine drugs, various, at Springdale, W. Dist. Ark.

Charged 6-8-65: while held by Carol C. Worthing, D.V.M., Springdale, Ark., the labeling lacked adequate directions for use and the articles were not exempt as prescription drugs, since they were not for use or dispensing in professional practice; 502(f)(1). Default decree ordered the articles held, pending final order of destruction. (55)

Amphetamine tablets, at Kansas City, Dist. Kans.

Charged 6-7-65: while held by David Shelton, truck driver, the labeling of the articles lacked adequate directions for use and were not exempt as prescription drugs, since the possessor was not a regular and lawful dealer in such drugs, and the articles were not to be lawfully dispensed; 502(f)(1). Default decree ordered destruction. (56)

Pentrate-3 tablets, at Oswego, Dist. Kans.

Charged 3-24-65: when shipped by Bush Laboratories, St. Louis, Mo., the strength of the article was deficient and the label false and misleading, since the article was deficient in pentazetrithiol tetranitrate (approx. 39 percent); 501(c), 502(a). Default decree ordered destruction. (57)

Rauwolfia serpentina tablets, N.F., at Washington, Dist. Columbia.

Charged 3-28-66: while held for sale, the quality of the article was deficient as to tablet disintegration for coated tablets; 501(b). Default decree ordered destruction. (58)

Medical Fluid 960, at Mesquite, N. Dist. Tex.

Charged 3-23-65: when shipped by Dow Corning Corp., Hamlock, Mich., the article was a new drug without an effective New Drug Application and was not exempt, since it did not comply with regulations with respect to new drugs for investigational use; and the labeling of the article failed to bear adequate directions for use and it was not exempt as a bulk drug for manufacture, since compliance with the exempting regulations was lacking; 505(a), 502(f)(1). Default decree authorized release to FDA. (59)

Fetal tissue, sheep, Lyocell, at Phoenix, Dist. Ariz.

Charged 9-27-65: when shipped by Pinco, Inc., Laguna Beach, Calif., the article was a new drug without an effective New Drug Application, and no notice of claimed investigational exemption had been filed; the labeling contained false and misleading representations that the article was a drug for investigational use; and the labeling lacked adequate directions for use, since it was a new drug lacking an effective New Drug Application and the article did not comply with the exempting regulations for investigational drugs; 505(a), 502(a), 502(f)(1). Default decree ordered destruction. (60)

Bimethylpitylsiloxane fluid, at Beverly Hills, S. Dist. Calif.

Charged 4-19-65: while held by Harvey D. Kagan, M.D., Beverly Hills, Calif., the labeling of the article, which the holder had repacked into unlabeled bottles for use by injection into humans, lacked adequate directions for use and was not exempted, since it lacked required information for use by licensed practitioners; 502(f)(1). Default decree ordered destruction. (61)

Nepcezyme tablets, at Wyandotte, E. Dist. Mich.

Charged 11-13-64: while held by New England Pharmacal Co., Wyandotte, Mich., the labeling of the article, which had been manufactured locally for the dealer from arginase shipped in interstate commerce, contained false and misleading therapeutic claims; and the article's labeling lacked adequate directions for use, since the article was a new drug and its labeling was not authorized by an effective New Drug Application; 502(a), 502(f)(1), 505. After New England Pharmacal Co. claimed the article, and filed an answer, the court granted the Government's motion for judgment on the pleadings, found the article misbranded under 502(f)(1), and ordered the article destroyed. (62)

Bandage, adhesive, absorbent, sulfathiazole pads, U.S.P. Blue Cross, at Athol, Dist. Mass.

Charged 5-5-65: when shipped by Hampton Manufacturing Co., New Rochelle, N. Y., the article's quality and purity were deficient, and the labeling false and misleading as to sterility, since the article was contaminated with living micro-organisms; and the article lacked the prescription legend; 501(b), 502(a), 503(b)(4). Default decree ordered destruction. (63)

Bandages, nonadhesive gauze, U.S.P., at Los Angeles, S. Dist. Calif.

Charged 9-2-65: while held for sale, the quality and purity of the article were deficient and the label false and misleading as to sterility, since the article contained mold; 501(a)(1), 501(b), 502(a). Default decree ordered destruction. (64)

DRUGS / Veterinary

Iodine Tincture, Strong, Non-Official, veterinary, at Phoenix, Dist. Ariz.

Charged 12-28-65: when shipped by Albion Veterinary Supply, the article labeled "Strong Iodine Tincture (Non-Official)" . . . Distributed by Beck's Dairy Supply Co. . . had been manufactured, processed, packed, and held under conditions lacking current good manufacturing practice; and the strength of the article was deficient and the label was false and misleading as to amount, since the article was deficient in iodine and potassium iodide (approx. 28 percent iodine and approx. 22 percent potassium iodide); 501(a)(2)(B), 501(c), 502(a). Default decree ordered destruction. (65)

Procaine penicillin, veterinary, U.S.P., at Kansas City, W. Dist. Mo.

Charged 5-14-65: while held by Edwards Veterinary Supply Co., Kansas City, Mo., the strength of one lot of the article was deficient and the labeling false and misleading as to strength, since the article was deficient in penicillin (approx. 16 percent), and no antibiotic certificate or release was in effect for both lots, since the expiration date for the drug had passed; 501(b), 502(a), 502(i)(2). Default decree ordered destruction. (66)

MEDICAL DEVICES

Electro-therapy device, Rose, at Atlanta, N. Dist. Ga.

Charged 12-14-65: when shipped by Rose Electro-Therapy Manufacturing Co., Los Angeles, Calif., the accompanying labeling contained false and misleading therapeutic claims; and the article was dangerous to health when used as directed by its labeling; 502(a), 502(j). Default decree authorized release to FDA. (67)

Vibrating and heating chairs, pads, and other units, Niagara, at Denver, Dist. Colo.

Charged 4-15-65: while held by Niagara of Colorado, Denver, Colo., the accompanying labeling contained false and misleading therapeutic claims; and the labeling of the articles lacked adequate directions for the therapeutic uses for which the articles were offered by Mel Hopf, salesman for Niagara of Colorado; 502(a), 502(f)(1). Default decree authorized donation of 3 chairs, after all electrical units were

removed, to public/charitable institution, and release of the remainder of the articles to FDA. (84)

Vibrating and heating chairs, and other units, Niagara, at Denver, Dist. Colo.
Charged 3-10-65: when shipped by Niagara Therapy Manufacturing Corp., Los Angeles, Calif., and Brocton, N.Y., the accompanying labeling contained false and misleading therapeutic claims; and while held by Niagara of Colorado, Denver, Colo., the articles' labeling lacked adequate directions for the therapeutic uses for which the articles were offered by Mel Hopf, salesman for Niagara of Colorado; 502(a), 502(f)(1). Default decree authorized donation of 4 chairs to public/charitable institution, and release of remaining devices to FDA. (89)

Vibrating and heating chairs, pads, and other units, Niagara, at Denver, Dist. Colo.
Charged 7-16-65: while held by Niagara of Colorado, Denver, Colo., the labeling lacked adequate directions for the therapeutic uses for which the articles were offered by Cyril Ruder and Melvin Hopf, salesmen for Niagara of Colorado; 502(f)(1). Default decree authorized release to FDA. (70)

Exercise device, electronic, Figurecare, at St. Paul, Dist. Minn.
Charged 12-10-65: while held by Figurecare, St. Paul, Minn., the labeling lacked adequate directions for the therapeutic uses for which the article was offered by Mrs. Irene Rice, a sales representative of the dealer; 502(f)(1). Default decree authorized release to FDA. (71)

Back aid device, Mark Fore, at Portland, Dist. Maine.
Charged 3-14-66: when shipped by Market Forge Co., Everett, Mass., the labeling contained false and misleading statements and therapeutic claims; 502(a). Default decree ordered destruction. (72)

Slant boards, Dr. Jensen's, at Phoenix, Dist. Ariz.
Charged on or about 5-13-66: when shipped by Bernard Jensen Products, Solana Beach, Calif., the accompanying labeling contained false and misleading therapeutic claims; 502(a). Default decree ordered destruction. (73)

Bath-pump device, Aquassage Whirlpool, at Joplin, W. Dist. Mo.
Charged 9-30-65: when shipped by Dakon Corp., New Hyde Park, N.Y., the accompanying labeling contained false and misleading therapeutic claims; 502(a). Default decree ordered destruction of the accompanying labeling and authorized donation of the devices to public/charitable institution. (74)

Vacuum cleaner, Filter Queen, at Fresno, S. Dist. Calif.
Charged 5-3-65: while held for sale, the labeling of the article lacked adequate directions for the therapeutic uses for which the article was offered by E. Ludvickson, representative for Regina Fresno Agency, Fresno, Calif.; 502(f)(1). Default decree authorized release to FDA. (75)

PROPHYLACTICS

Prophylactics, rubber, at Chicago, N. Dist. Ill.
Charged 7-5-66, amended 8-2-66: when shipped from London, England, New York, N. Y., Northfield, Ohio, Chicago, Ill., or Newark, N. J., the quality of the article, which had been repacked locally from commingled lots, was deficient and the labeling false and misleading, since the article contained holes (approx. 2.3 percent); 501(c), 502(a). Default decree ordered destruction. (76)

Prophylactics, rubber, at Fort Worth, N. Dist. Tex.
Charged 3-30-66: when shipped by Barnett's, Inc., the quality of the article was deficient and the labeling false and misleading, since it contained holes (approx. 0.7 percent); 501(c), 502(a). Default decree ordered destruction. (77)

Prophylactics, rubber, Royal Knight, at Columbia, Dist. S.C.
Charged 4-18-66: when shipped by Allied Latex Sales Co., Inc., the quality of the article was deficient and the labeling false and misleading, since it contained holes (approx. 0.9 percent); 501(c), 502(a). Default decree ordered destruction. (78)

HAZARDOUS SUBSTANCES

Ceramic glaze remover, Gold-Off, at Stewartville, Dist. N.J.
Charged 3-22-65: when shipped by Etchall, Inc., Columbia, Mo., the article was an eye irritant and corrosive substance containing ammonium bifluoride (approx. 21 percent), and its containers lacked a number of the required conspicuous label statements; 2(p)(1) (B,C,E,F,G & J). Default decree ordered destruction. (79)

Penetrant oil, Loese'n It, at Gas City, N. Dist. Ind.
Charged 7-19-65: when shipped by Spee-Dee Chemical Products Co., Davison, Mich., the article was a toxic substance presenting a special hazard because of its petroleum distillate content, and its containers lacked a number of the required conspicuous label statements; 2(p)(1) (B,E & F), 3(b). Default decree ordered destruction. (80)

Water Repellent, X-33, 7 seizure actions, at Somerville, Sudbury, Brookline, and Sharon, Dist. Mass., Vestaburg, W. Dist. Mich., and Waterboro, Dist. Maine.
Charged between 5-14-64 and 2-15-65: when shipped by Wilmington Chemical Corp., Chicago, Ill., the article was an extremely flammable substance, and its containers lacked a number of the required conspicuous label statements; 2(p)(1)(E,F & I). Default decree ordered destruction. (81)

7 seizure actions, at Columbus and Owensville, S. Dist. Ind., Wenatchee, E. Dist. Wash., Rice Lake, W. Dist. Wis., Monroe, Dist. Maine, Bloomer, W. Dist. Wis., and Kamrar, N. Dist. Iowa.
Charged between 3-22-65 and 5-27-65: when shipped by Wilmington Chemical Corp., Chicago, Ill., the article was an extremely flammable substance, and some of its containers lacked 6 of the required conspicuous label statements; and other containers lacked 3 of the required conspicuous label statements; 2(p)(1)(B,C,E,F,G & I), 2(p)(1) (E,F & I). Default decree ordered destruction. (82)

12 seizure actions, at Farnam, Ainsworth, Valentine, Mullen, Elba, Loup City, Sargent, Ord, Scotia, Table Rock, Eddyville and Kimball, Dist. Nebr.
Charged 12-3-65: when shipped by Wilmington Chemical Co., Chicago, Ill., the article was an extremely flammable substance, and its containers lacked a number of the required conspicuous label statements; 2(p)(1)(E,F & I). Default decree ordered destruction. (83)

20 seizure actions, at Rolla, E. Dist. Mo., Wellesley, Dist. Mass., Alliquippa, W. Dist. Pa., Gallatin, W. Dist. Mo., Benton, E. Dist. Ark., Suver, Dist. Oreg., Greensburg, S. Dist. Ind., Omak, E. Dist. Wash., Milo, Dist. Maine, Ellsworth and Richmond, W. Dist. Wis., Aberdeen, Dist. S. Dak., Lewistown, Dist. Mont., Connell, E. Dist. Wash., Jeffersonville, S. Dist. Ohio, Lake Providence and Vidalia, W. Dist. La., Eva, N. Dist. Ala., Pittsfield, Dist. Maine, and Alamo, Dist. N. Dak.
Charged between 4-1-64 and 4-22-65: when shipped by Wilmington

Chemical Corp., Chicago, Ill., the article was an extremely flammable substance, and its containers lacked a number of the required conspicuous label statements; 2(p)(1)(E,F & I). Default decree ordered destruction. (84)

NOTICES OF JUDGMENT on Criminal Cases

UNFIT FOOD

George H. Leach, t/a Plainview Canning Co., Plainview, N. Dist. Tex.

Charged 8-3-66: when shipped, canned tomatoes contained decomposed tomato material and contained excessive tomato peel; 402(a)(3), 403(h)(1). Guilty plea; fine. (85)

Brinkley & Co., Inc., and Henry W. Brinkley, president, Petersburg, E. Dist. Va.
Charged 7-18-66: flour was held in a building accessible to rodents and contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (86)

Lederman Bros. Bakery, Inc., and Beryl Lederman, president, Worcester, Dist. Mass.
Charged 1-19-66: flour was held in a building accessible to insects and contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (87)

PRESCRIPTION DRUGS

Andrew J. Persich and Anthony Di Donato, Peoria, S. Dist. Ill.

Charged 9-23-64: conspiracy to dispense amphetamine-containing tablets without a prescription; and amphetamine sulfate tablets and desoxyephedrine hydrochloride tablets were dispensed without a prescription; 18 U.S.C. 371, 503(b)(1). Guilty plea by Persich; fine and probation. Guilty plea by Di Donato; fine, plus costs. (88)

William E. Johnston, t/a Willis Pharmacy, Detroit, E. Dist. Mich.
Charged 5-11-65 by grand jury: penicillin tablets and Enovid tablets were dispensed without prescription; 503(b)(1). Guilty plea; imprisonment under 21 U.S.C. 4208(b). (89)

Dwight M. Hoke, M.D., Beckley, S. Dist. W. Va.
Charged 3-7-66: meprobamate tablets were dispensed without prescription; 503(b)(1). Guilty plea; probation. (90)

Paul Cole, t/a Paul Cole Drug Co., and Thomas F. Evans, pharmacist, LaGrange, N. Dist. Ga.
Charged 5-4-66: Librium capsules and Equanil tablets were dispensed as unauthorized refills; 503(b)(1). Nolo contendere pleas; fines. (91)

Arthur C. Bryant, truck stop owner, and James E. Walker, truck stop manager, Richmond Hill, S. Dist. Ga.
Charged 11-1-65: secobarbital sodium capsules, pentobarbital sodium capsules, penicillin tablets, and dextro-amphetamine sulfate tablets were dispensed without prescription; 503(b)(1). Guilty plea by Bryant; fine and probation. Nolo contendere plea by Walker; fine and probation. (92)

Joe Simmons, t/a Joe Simmons Cafe & Truck Stop, and Donnie Simmons, truck stop employee, Robertsedale, W. Dist. Ala.
Charged 5-3-66: dextro-amphetamine sulfate tablets and desoxyephedrine hydrochloride tablets were dispensed without prescription; 503(b)(1). Guilty plea by Donnie Simmons; probation. Guilty plea by Joe Simmons; imprisonment and probation. (93)

Leland F. Anderson and Wayne S. Anderson, partners in a drug store, Carlisle, S. Dist. Ind.
Charged 7-15-66: Librium capsules and Diuril tablets were dispensed without prescription; 503(b)(1). Nolo contendere pleas; fines. (94)

Armen Boswell Neel, Sr., t/a Neel's Pharmacy, and Clifton C. O'Brien, pharmacist, Griffin, N. Dist. Ga.
Charged 5-4-65: Biphedamine 12½ capsules were dispensed as unauthorized refills; 503(b)(1). Nolo contendere pleas; fines and probations. (95)

Harris Medical Center Pharmacy, Inc., Edward J. Bernstein, president and treasurer, and Ugo Giannasi, William J. Cizek, and Eugene A. Pederzoli, Jr., pharmacists, Springfield, Dist. Mass.
Charged 3-25-65: Premarin tablets were dispensed without prescription, and Dextedrine Spansule capsules and Miltown tablets were dispensed as unauthorized refills; 503(b)(1). Guilty plea by corporation; fine. Guilty pleas by individuals; fines, suspended sentences, and probations. (96)

Thomas H. Goldberg, t/a Thomas H. Goldberg's Chemist Shop, and Walter E. Colvin, pharmacist, Providence, Dist. R.I.
Charged 3-10-66: Butisol Sodium tablets and Dextedrine Sulfate tablets were dispensed as unauthorized refills; 503(b)(1). Guilty pleas; fines. (97)

Freeman Drug Co., a partnership, Joseph C. Freeman, partner, and Robert M. Lee, pharmacist, LaGrange, N. Dist. Ga.
Charged 5-4-66: Enovid tablets were dispensed without a prescription, and Equanil tablets and Biphedamine 20 capsules were dispensed as unauthorized refills; 503(b)(1). Nolo contendere pleas; partnership and Lee, fined; Freeman, fine and probation. (98)

Georgia-Mableton Drug Corp., t/a Liggett-Rexall Drugs, Joe A. Bellow, pharmacist-manager, and Eddie Frank Daniel, pharmacist, Mableton, N. Dist. Ga.

Charged 5-11-66: Miltown tablets and Dextedrine Sulfate tablets were dispensed as unauthorized refills; 503(b)(1). Nolo contendere pleas; fines. (99)

Herbert Oelschlegel, t/a Thrifty Drug #1, at Corpus Christi, S. Dist. Tex.
Charged 11-22-65 as violation of probation: quinidine sulfate tablets, quinine sulfate tablets, thyroid tablets, progesterone tablets, endothyrin tablets, and Benztrol tablets were dispensed without a prescription; 503(b)(1). The court found probation had been violated, revoked probation, and imposed imprisonment. (100)

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

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

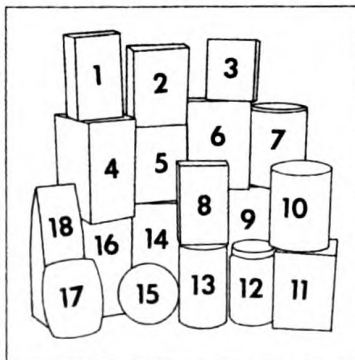
JAMES L. GODDARD, Commissioner of Food and Drugs.

WASHINGTON, D. C., March 1, 1967.

Fair packages



THEY WEAR THEIR LABELS WITH DISTINCTION Consumer Specialists in FDA's 18 Districts are distinguished for their professional training and for leadership in behalf of the American consumer. They provide a two-way channel of communication . . . explaining the life-protection mission of FDA to professional and consumer groups and reporting consumer needs and attitudes back to FDA.



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OFFICIAL BUSINESS

Announcements

THE FOOD AND DRUG LAW INSTITUTE, INC., will hold a Second Annual One-Day Seminar on "Legal Guidelines for Self Regulation in Advertising, Labeling and Promotion of Drugs" at the School of Law, Northwestern University, Chicago, Ill., April 14.

The meeting "... will afford members of the legal, medical, advertising and promotional staffs of pharmaceutical manufacturing concerns and their advertising agencies, an opportunity to bring up-to-date their own information in this important area. It will provide, too, a special opportunity for Midwestern staff who were unable, because of time and distance involved, to attend the earlier Eastern program," said FDLI President, Franklin M. Depew.

The panel of experts will include Dr. R. S. McCleery and H. W. Chadduck, Division of Medical Advertising, FDA; Mr. J. K. Kirk, Associate Commissioner for Compliance and J. Hauser of that FDA office.

Representing industry is David Sutton, V. P. Marketing, Arnar Stone Labs., and President of the Midwest Pharmaceutical Advertising Club; Warren Whyte, Attorney, Abbott Labs.; Arthur Wright, Attorney, Baxter Labs.

S. H. Willig, FDLI, will be the principal lecturer. Mr. Willig is Professor of Drug Law at Temple University. "Professor Willig enjoys the respect of industry heads and government officials for his objective and reasonable approach to effectuate compliance with the Act and its auxiliary regulations, and is called upon frequently for assignments and consultations," said Mr. Depew.

Pre-registration prior to April 1 is recommended. The \$25 registration fee includes luncheon. Write: Franklin M. Depew, President, Food and Drug Law Institute, Inc., 205 East 42nd Street, New York, N. Y. 10017.

FDA INDUSTRY WORKSHOPS During March and April, 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 further information should contact the nearest District or BDAC Field Office.

SCHEDULE OF FDA WORKSHOPS AND CONFERENCES / MARCH & APRIL 1967

FDA District or BDAC Field Office	Date	Location	Subject Area
Atlanta	March	Atlanta, Ga.	Drugs—GMP
	March 15	Atlanta, Ga.	Sanitation in Food Warehousing
Boston	March 28	Boston, Mass.	Drugs—GMP
	March 30	Hartford, Conn.	Drugs—GMP
Buffalo	March 7	Albany, N.Y.	Drugs—GMP
	March 9	Syracuse, N.Y.	Drugs—GMP
	March 14	Pittsburgh, Pa.	Drugs—GMP
	March 16	Buffalo, N.Y.	Drugs—GMP
Kansas City	March 14	Manhattan, Kans.	Medicated Feeds
	March 29	Ames, Iowa	Salmonella in Dried Milk
	March 31	Lincoln, Nebr.	Salmonella in Dried Milk
New Orleans	March 9	Mobile, Ala.	Pecan Shellers
St. Louis	March 2	Little Rock, Ark.	Sanitation in Food Warehousing
Seattle	March	Northwest	Canned & Frozen Foods with Northwest Cannery & Freezers
	March 20-21	Corvallis, Oreg.	Drugs—GMP and Drug Abuse Control
Baltimore	April	Richmond, Va.	Canned Foods
Detroit	April 11	Michigan	Drugs—GMP
(Jointly with Cincinnati District)	April 17	Columbus, Ohio	Drugs—GMP
(Jointly with Cincinnati District)	April 20	Lafayette, Ind.	Drugs—GMP
Philadelphia	April 5	Philadelphia, Pa.	Drugs—GMP
	April 6	Philadelphia, Pa.	Drugs—GMP