

FDA **CONSUMER**

MAY 1975



Making
Cosmetics Labeling More Than
Skin Deep



This Month

If knowledge is power, consumers who go out to buy laxatives or cosmetics will be better armed as a result of two FDA actions that are the subject of articles in this month's issue.

As part of its continuing review of over-the-counter (OTC) drugs, FDA has published the report of its Advisory Panel on OTC Laxatives, Antidiarrheal, Emetic, and Antiemetic Drug Products. Ultimately, the report will become the basis for FDA standards on what constitutes safe and effective ingredients for laxatives and the other products covered by the study, and what claims can be made on the labels of these products. But the final standards won't be forthcoming until FDA has had an opportunity to review thoroughly the comments from the public and the drug industry that are now coming in on the report. In the meantime, consumers will find that the report is the source of much valuable information about laxatives and their proper use.

If a complete record of the use of cosmetics were compiled, it probably would have to go back almost to the beginning of human history. And although a great deal of material would be available on the rituals, ceremonies, and everyday customs in which cosmetics have played a part, lists of ingredients that have gone into specific cosmetics down through the years might be hard to come by. There has always been an aura of mystery about these creams, powders, and ointments, whether they are old family recipes or the formulations behind familiar commercial products. There will be less mystery in the future, however, now that FDA has issued final regulations on cosmetic labeling.

Generally, the new regulations require the label of every cosmetic to list the substances that went into it. If a product might be hazardous, certain warning or cautionary statements are required. Ingredients that are trade secrets won't have to be listed, but before such an exception is granted, FDA will have to verify that a bona fide trade secret is indeed involved. For a run-down on what the new regulations require, and when, see "Making Cosmetics Labeling More Than Skin Deep" and "Helping the Consumer Play Safe."

Inside Front Cover Photo: *Laxatives come in a variety of forms, but one thing many have in common is that they are supposed to promote "regularity." Many people apparently believe that the bowel should function with something approaching clocklike precision. This misconception, says an FDA advisory panel, has led to "widespread overuse of self prescribed laxatives." A report on the panel's findings begins on page 16.*

FDA **CONSUMER**

VOL. 9 NO. 4 / MAY 1975

Getting on the Right Track	4
Making Cosmetics Labeling More Than Skin Deep	10
Helping the Consumer Play Safe	13
Laxatives: What Does 'Regular' Mean?	16
DDT Residues in Food Decline	22
News Highlights	24
Regional Reports	26
State Actions	29
Seizures and Postal Service Cases	30
Notices of Judgment	32

Caspar W. Weinberger
Secretary, U.S. Department of
Health, Education, and Welfare

Theodore Cooper, M.D.
Assistant Secretary for
Health

Alexander M. Schmidt, M.D.
Commissioner of Food and Drugs

John T. Walden
Assistant Commissioner
for Public Affairs

Ellis Rottman/Editor

Harold C. Hopkins/Editorial Director

Jesse R. Nichols/Art Director

Joan M. Galloway/Managing Editor

Frederick L. Townshend/Production Manager

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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 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.

Cover Design: Zeb Rogerson

Consumer Forum

Drug Controls Not Final

I read with interest the article entitled "‘Cooling It’ on Tranquilizers" in the April, 1975, issue of FDA CONSUMER. While I agree with the overall intent of the article to educate patients about the controls contemplated for the drugs mentioned, I believe it should be emphasized that the Drug Enforcement Administration (DEA) has not published a final order to move the drugs into Schedule IV (a category of controls under the Comprehensive Drug Abuse Prevention and Control Act). A proposal was published on January 27, 1975, but

a final order has not yet appeared. Hence, contrary to the impression created in the article, the drugs are not subject to DEA controls yet.

Joseph L. Fink, III

Assistant Professor of Pharmacy Administration
The Philadelphia College of Pharmacy and Science
Philadelphia, Pennsylvania

Mr. Fink is correct; the final order had not been published at the time the article appeared. Numerous comments were received by DEA on the proposed order and had to be reviewed and considered before publication of a final order. This process has been completed and DEA has issued a final order. The controls referred to in the FDA CONSUMER article will be in effect by mid-July. FDA CONSUMER regrets the error.

Quotes

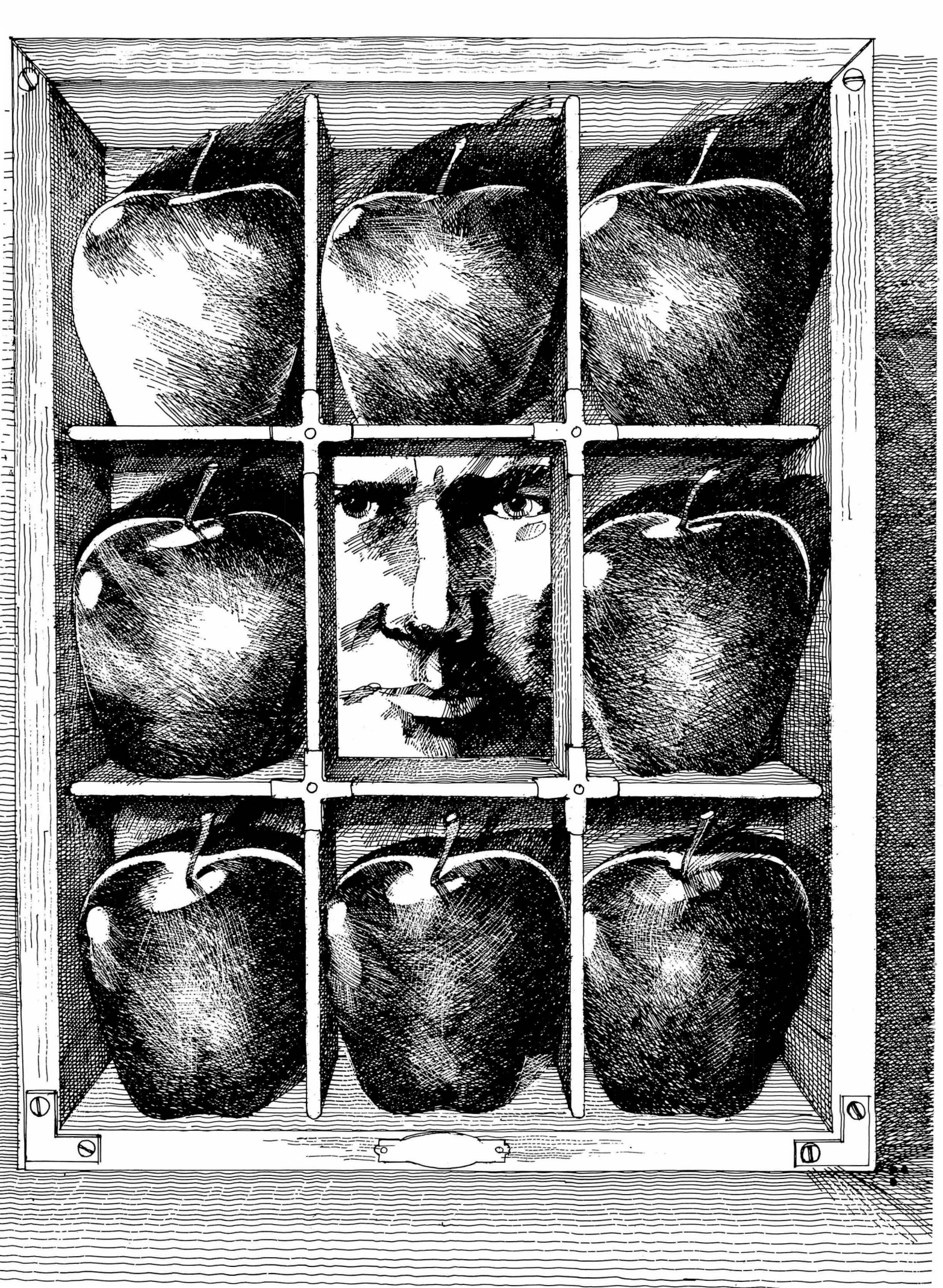
“Universal concern for abundant and economical supplies of food must convince us that we need to examine all available alternatives to keep food production abreast of world needs. In a period of famine abroad and economic dislocation at home, we can afford less than ever the loss of available food through misprocessing, mishandling, faulty packaging, or storage. Two FDA programs, Hazard Analysis of Critical Control Points (HACCP) Inspections and Cooperative Quality Assurance, seek to avoid such errors and thus prevent the need for massive food recalls—so costly to industry, consumers, and FDA.

“The HACCP system is an inspectional approach that utilizes inspectors specially trained to analyze and evaluate complex production processes. An HACCP inspection can identify deficiencies in manufacturers’ quality controls and thereby prevent the production and marketing of unsafe foods. Had this technique been fully operative before August 1972, FDA could have received warning signals indicating the need for revised quality control procedures in the mushroom industry before a major crisis developed.

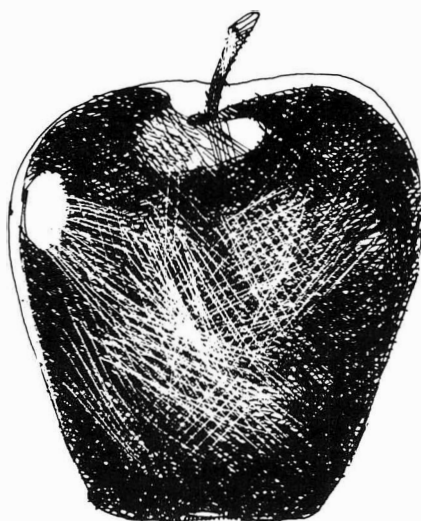
The HACCP technique has since been used in inspections of plants producing low acid canned foods, frozen ‘heat and serve’ dinners, and frozen packaged fish and shellfish—all of which are considered as primary sources of foodborne illness.

“FDA’s Cooperative Quality Assurance is a voluntary program that includes some of the country’s major food firms. The participating plants provide FDA with their quality control and processing specifications, and they agree to report any exceptions or deviations from these specifications. FDA, in turn, reviews this information and advises manufacturers of quality control changes that should be made to increase the assurance of marketing safe products. A related approach used for communication with the food industry involves the development and implementation of Good Manufacturing Practices (GMP) standards for food firms. FDA has implemented a basic umbrella GMP, and more specific GMP’s for low-acid canned food, smoked fish, breaded shrimp, confectionary products, and bottled water. These standards have already been published as proposals or final orders.”

Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, before the Subcommittee on Agriculture and Related Agencies of the House Appropriations Committee



Getting On The Right Track



Public surveys help FDA determine how the products it regulates affect the consumer and the extent of consumer concerns and knowledge about these products.

by Harold C. Hopkins

Epitaph in a western cemetery: "Here lies John Williams. He done his damndest."

Most of us like to think we are doing ours. But a Government agency, unlike an ordinary business, cannot point to its profit and loss statement or declare a dividend to demonstrate that it is on the right track. What it is doing, right or wrong, may come to ultimate accounting only when the people ex-

press themselves at the voting booth and the legislative mills begin grinding out Federal statutes, public policy, and money appropriations.

Where human health and the consumer's economic welfare are at stake, however, that is almost never soon enough. Accordingly, FDA in recent years has looked for ways to keep in closer contact with consumers—the intended beneficiaries of its protective efforts—to find whether they are in fact getting everything the law entitles them to and whether they know how to look out after their own interests in buying or using products regulated by the Agency.

One significant method FDA has been using increasingly to keep in touch is the public survey, intended to determine how the products FDA regulates affect the consumer and to find out the consumer's concerns and degree of knowledge about these products. Public surveys have been used successfully by many modern corporations to learn whether the public is likely to accept a newly marketed product, a change in formula, or a new package design. Similar methods have long been in use by the Bureau of the Census to assess the state of the economy or culture and by political pollsters to determine the mood or concerns of the electorate.

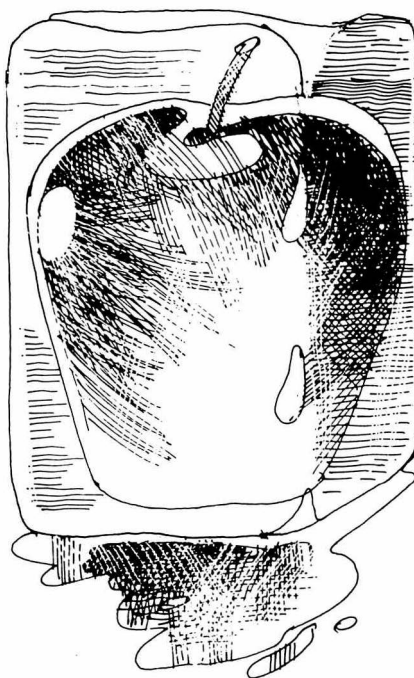
A public survey consists essen-

tially of personal interviews or mailed questionnaires asking specific questions to get information on one or more subjects. Survey respondents are selected to form a sample or cross-section of consumers that will be representative of the consuming public as a whole. Some surveys direct questions to specific population categories on various questions concerning the public, such as to physicians on adverse reactions to types of drugs. The responses are then evaluated and the information used to form certain conclusions about the respondent group that can be considered representative of a larger group with a high degree of accuracy.

Information obtained through public surveys helps FDA to make informed judgments in deciding whether to take a specific action or adopt a new policy; to bring out a new regulation or change an existing one to assure better protection; or to undertake an educational campaign that will acquaint the public with important information concerning health, safety, or economics involving regulated products.

What FDA learns from a public survey may constitute the major basis for an agency action or may be one of several factors the Agency considers in deciding what to do and how to do it.

Several FDA public surveys have been in the field of nutrition and nutrition labeling. A comprehensive survey that took several years and was completed in 1972 on the health practices and opinions of Americans indicated that most consumers are highly susceptible to false or misleading health claims made both for drugs and for vitamin-mineral food supplements and so-called health foods (FDA CONSUMER, October 1972). Information from this survey, which was funded by FDA and other organizations, has been helpful to FDA



**Those who thought
preservatives not at
all safe increased from
7 percent in 1966 to
17 percent in 1972.**

in establishing justification and principles for promulgation of its series of regulations on nutrition labeling and in reviewing over-the-counter drug label claims.

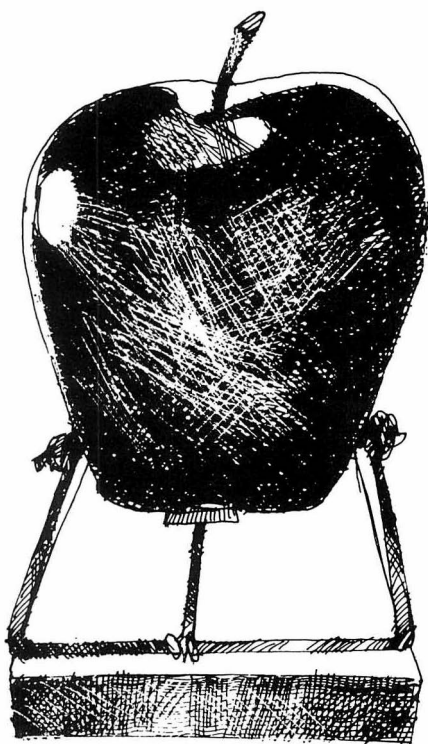
Another earlier study indicated general confusion about the percentage of orange juice consumers thought should be in the beverage called orange juice drink, and led to FDA regulations requiring that the name of the product include a statement of the percentage of orange juice in it.

Two surveys completed in 1966 and 1972 show some interesting trends during a period when consumers were becoming more and more concerned about environmental problems and about what they eat and drink. Parts of the two surveys included consumer opinions about the safety of foods; of foods containing pesticide residues, artificial coloring, and preservatives; and of prescription and over-the-counter (nonprescription) drugs.

The portion of respondents who were definitely or reasonably sure that foods are wholesome and pure dropped from 82 percent in 1966 to 78 percent in 1972. This suggests that consumers may have become less positive in their attitudes by 1972 and qualified their confidence in food safety more than they did 6 years earlier. Respondents were asked to give a numerical rating to their concerns about the safety of foods containing various chemical substances. The rating scale of 1 to 6 ranged from "very safe" at the top to "not at all safe" at the bottom.

Those who thought foods to be "very safe" as concerns pesticide residue content constituted 24 percent of the total in 1966, but only 5 percent in 1972. Those who felt foods with pesticide residues were unsafe constituted only 8 percent in 1966, 19 percent in 1972.

Foods containing artificial colors



The confidence of people in the wholesomeness and purity of food appears to have become more qualified by 1972 than it was 6 years earlier.

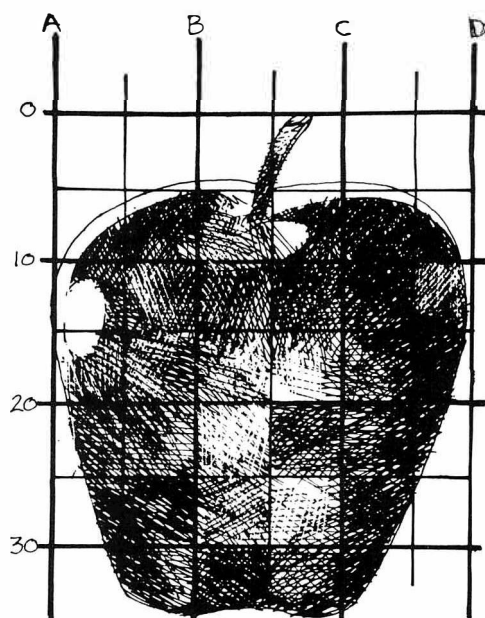
were considered "very safe" by a projected 41 percent of the population in 1966 compared to 15 percent in 1972, while the portion considering them "not at all safe" increased from 9 to 13 percent.

Those who thought foods containing preservatives were very safe constituted 33 percent in 1966, but only 7 percent in 1972. Those who thought preservatives not at all safe increased from 7 percent in 1966 to 17 percent in 1972. (This part of the survey was described in FDA CONSUMER, June 1973.)

Other results showed that respondents who thought over-the-counter drugs very safe decreased from 26 percent in 1966 to 9 percent in 1972, while over the same period those who thought them not at all safe remained at 12 percent. For prescription drugs, 67 percent thought they were very safe in 1966 but only 44 percent thought so in 1972, while 1 percent thought not at all safe in 1966 and 2 percent in 1972. (This part of the study was described in FDA CONSUMER, May 1973.)

A study completed in 1970 on consumer concepts and expectations about vitamin and mineral supplements, fortified foods, and foods for special diets found that a significant portion of the public was confused, misinformed, or uninformed about the relationships to health of these products, and that label declarations influence selection of food purchases.

Before issuing its nutrition labeling regulations, FDA sought to determine consumer reactions to and comprehension of several possible methods or formats for listing nutrition information on food labels. The study, completed in June 1972, found that the most acceptable and understandable method was one listing nutrients in the food according to the percentage, contained in each serving, of the total daily allowance of each nutrient recom-



A number of surveys indicated considerable public confusion over the vitamin and mineral content of foods.

mended by the Food and Nutrition Board of the National Academy of Sciences-National Research Council. This format was adopted by FDA in its final regulations. The study also found that some economic and age groups would be more likely than others to use nutrition information put on labels; that most consumers would be willing to pay slightly higher prices for foods to obtain this information; and that respondents generally believed that use of such labeling by manufacturers would be an incentive to manufacturers to provide more nutritious foods.

A public survey on informative labeling, completed in 1973, found that 86 percent of shoppers read the labels on foods purchased and that 67 percent are concerned with economic factors such as price, volume, or weight when buying packaged foods for the first time (FDA CONSUMER, February 1974).

In a study completed in 1974 on the level of consumer knowledge about nutrition labeling, 75 percent of the respondents said they would use nutrition labeling in deciding whether to purchase new brands of food. Most respondents said they would prefer nutrition labeling, if provided, over recipes to occupy the available label space on a container, and 67 percent said they would be willing to pay as much as 30 cents a week in increased food product costs for nutrition labeling if they had to. (This survey was described by articles in the July-August, September, and October 1974 issues of FDA CONSUMER.)

FDA completed surveys in 1974 on ways to communicate with physicians to provide them important information about specific drugs or types of drugs. The study found that FDA's Drug Bulletin, which is mailed periodically to doctors to bring them up to date with recent information on drugs, enjoys greater readership among the responding



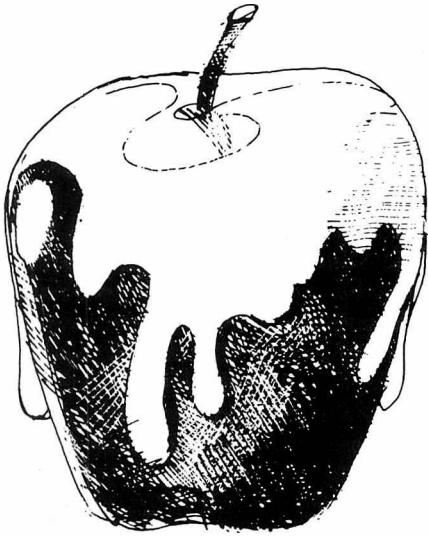
**Survey information
has been helpful to
FDA in establishing
regulations on nutrition
labeling and contents
designations.**

physicians than any other periodical newsletter among those surveyed. The physician respondents considered the Drug Bulletin generally informative and interesting, and 93 percent wished to continue receiving it. Of the respondents, 43 percent said the Drug Bulletin had influenced their prescribing practices.

One continuing public survey, which has established a system for reports by hospitals and pharmacies on defects they found in checking drugs before use (FDA CONSUMER, July-August 1974), has had more lasting benefits than the initial information it gathered. The methods developed in the survey have formed the basis for a continuing FDA surveillance system that now collects, processes, and evaluates 5,000 to 6,000 drug defect reports a year and enables the Agency to direct regulatory attention to those companies or areas of the drug manufacturing industry that, in marketing defective drugs, may present threats to public health.

Nothing succeeds like success, and FDA's success in getting on the right track through use of public surveys has encouraged the Agency to use this technique for more and more questions calling for a high degree of knowledge about consumer needs and desires, as well as information that can come only from a special population group, such as physicians.

Public surveys are normally carried out under an FDA contract. The organization or group that actually conducts the survey, in coordination with the appropriate FDA bureau or other entity, may be a professional research organization, a foundation, a university, or sometimes another Government agency such as the Bureau of the Census. The two dozen or so public surveys completed or under way since 1965 have cost about \$1.7 million or an average of about \$68,000, ranging from about \$15,000 to \$270,000



Foods containing artificial colors were considered very safe by 41 percent of the population in 1966 compared to 15 percent in 1972.

per survey, depending on size, scope, complexity, and other variables.

Surveys or studies are currently in progress on: the knowledge and attitudes of elderly consumers about influenza vaccines; selection and use of oral contraceptives by women patients, their comprehension and use of patient package insert labeling, and the effect of this labeling on use of the products; effects of FDA's campaign to educate consumers in nutrition knowledge and planning of balanced diets;

a 4,000-household survey on family food intake during a 14-day period; consumer understanding of over-the-counter drug labels; consumer complaints about adverse reactions experienced with cosmetic products; and a study on the knowledge, beliefs, and attitudes of physicians and the use of para-professionals and of new educational techniques in diagnosis and treatment of hypertension.

Harold Hopkins is editorial director of FDA CONSUMER.

How To Obtain Survey Results

Following is a list of several published FDA public surveys. Listings followed by "NTIS" may be purchased for the cost noted from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22151 (when ordering, include the document number shown in the listing). Abstracts of the four reports followed by an asterisk (*) are also combined into Document FDA-D-ADMC-4, "Consumers and Medication," available from NTIS for \$4.

Food and Nutrition Knowledge and Beliefs. 1974. Available for \$5.50 from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402 (document HE 20-4002: N95/2/Parts 1 and 2).

The Need for Information on Adverse Drug Reactions, Including Reactions of Present and Potential Readers, to Clinical Experience Abstracts. 1974. NTIS, \$7 (document PB 234724).

A Survey of Drug Information Needs and Problems Associated With Communications Directed to Practicing Physicians. 1974. NTIS, \$6.75 (document FDA-D-ADMC-1).

Evaluation of the *FDA Drug Bulletin* Readership. 1974. NTIS, \$4.75 (document FDA-D-ADMC-2).

The Impact of Corrective Advertisements for Prescription Drugs. 1974. NTIS, \$4.75 (document FDA-D-ADMC-3).

A Study of Health Practices and Opinions.* 1972. NTIS, \$6 (document 210-978).

Study of Consumer Knowledge Levels Concerning Consumer Services and Benefits Received and Expected Under Laws Administered by the FDA* (perceived safety of food, food coloring and additives, and over-the-counter drugs). 1966.

Consumer Perception of Safety of Foods, Drugs, and Cosmetics.* 1972.

National Opinion Survey With Respect to Informative Food Labeling, Poison Prevention Packaging, and Drug Labeling.* 1973.



18

PHOTO

CALIFORNIA MILK
by MAX FACTOR
LEMON COLD CREAM
\$2.50
MOISTURIZER



Making Cosmetics Labeling More Than Skin Deep

by Harold C. Hopkins

Regulation on ingredients disclosure is designed to give consumers the kind of information they want and need to make better informed buying choices and to protect their health.

The eternal question about what little (and big) girls and boys are made of may remain unanswered, but we're due to learn more about the cosmetic aids that add to the excitement of this delightful guessing game. A new regulation will require cosmetic manufacturers to list on their labels the chemicals that make up the consumer's makeup. The only exceptions will be those ingredients that cosmetic companies claim are trade secrets, verified as such by FDA, and fragrances and flavors, an occult kingdom of chemical constituents whose large numbers, in FDA's opinion, can befuddle more than inform the ordinary consumer.

Cosmetic ingredient labeling is not intended to take the risk out of romance, nor even to satisfy normal curiosity. FDA believes the new regulation will give consumers the kind of information on cosmetics labels that many of them have been asking for so they can make better informed buying choices and pro-

tect their health. For instance, if a cosmetic contains a substance which has caused some consumers to have adverse allergenic reactions, they can learn of its presence and avoid that particular cosmetic. A physician looking for the source of an allergy problem in a patient may find cosmetic ingredient lists helpful in checking the various substances to which the patient has been exposed.

The new labels will not be seen in the market place immediately. Federal law requires FDA to give manufacturers a reasonable time to make label changes and to use up old labels. (Consumers may note, however, that some cosmetics already are carrying ingredient statements placed on labels voluntarily by some manufacturers in response to earlier requests by the Government, consumer organizations, and consumers.)

Under the new regulation, which is final subject only to any court test, ingredient statements must be carried on all cosmetic labels ordered by a manufacturer after March 3, 1976, and on all cosmetics manufactured after September 3, 1976.

Ingredients which the manufacturer claims, and FDA agrees, are company trade secrets, may be

referred to at the end of the listed ingredients by the general term, "and other ingredients," with no further explanation.

Fragrances or flavors, the other category of ingredients exempted from the required listing, need be referred to on the label only by the words "fragrance" or "flavor." A fragrance or flavor may contain a dozen or more additional ingredients of its own, and this plethora of extra names would, in FDA's opinion, just confuse consumers. It should be noted that many of these substances or compounds could probably qualify as trade secrets anyway were they not included in the fragrance or flavor exemption.

FDA said it is well aware that fragrances and flavors may contain substances that could cause adverse reactions in certain individuals and that it will welcome comments on this subject from the public as the basis for a possible future change in the regulation. The Agency is trying to determine whether certain fragrance or flavor ingredients that may cause harm should be listed on the label by their individual names to alert consumers who are susceptible to them.

So the consumer may have some idea about how much of a specific substance a cosmetic contains, the



FDA's regulatory responsibilities often require analyses of cosmetic ingredients.

ingredients are required to be listed in order of predominance in amounts. If a cosmetic is also a drug, the drug ingredients must be listed first. The regulation requires that the ingredients be listed by uniform names established especially for ingredient labeling to prevent mistaken identities, the use of different names to identify the same substance, and similar difficulties. FDA believes some consumers are familiar with many of the substances, but in the main, consumers will need to educate themselves about the significance, function, and properties of the various substances used in cosmetics.

The regulation permits the listing of small amounts of ingredients (concentrations of 1 percent or

less) and color ingredients of any amount in any order the manufacturer chooses. No listing is required for incidental ingredients if they are present at insignificant levels and have no technical or functional effect in the cosmetic.

FDA's statutory authority for requiring cosmetic ingredient labeling is not the Food, Drug, and Cosmetic Act, but the Fair Packaging and Labeling Act, which was enacted 9 years ago to prevent unfair or deceptive packaging or labeling of certain consumer commodities. Although no deception is intended, a cosmetic is of dubious value if it causes the purchaser to suffer an adverse reaction. Ingredient labeling will help consumers avoid such purchases. Thus the Fair Packaging

and Labeling Act is being used by FDA to offer consumers both pocketbook and health protection.

FDA began to address the problem of consumer concern over cosmetic product safety in 1972, when it adopted regulations providing for voluntary submission by cosmetic manufacturers to FDA of information as to the place of manufacture of a cosmetic, and lists of ingredients and raw materials. These regulations were adopted under authority of the Food, Drug, and Cosmetic Act.

Some of the comments FDA received on the voluntary regulations urged the Agency to require mandatory listing of cosmetic ingredients on labels. FDA pointed out that although this was not possible under the voluntary regulations then being considered, it was considering a proposal to require, under the Fair Packaging and Labeling Act, the listing on cosmetic labels of certain ingredients known to be the most frequent causes of adverse reactions.

Further comments and a proposal by the Consumer Federation of America in February 1973 maintained that under the Fair Packaging and Labeling Act FDA had authority to and should require listing of *all* ingredients on labels except those that are trade secrets. These arguments held that the consumer is entitled to know the contents of a cosmetic as much to calculate and compare values as to avoid buying those that could cause adverse reactions.

FDA agreed and published its mandatory ingredient labeling regulations in October 1973. After comments and objections, FDA proposed several amendments on March 3, 1975, to iron out technical difficulties involving the ingredient labeling of certain types of cosmetics. These provisions are scheduled to be adopted and to become effective at the same time as the rest of the regulation.

Harold Hopkins is editorial director of FDA CONSUMER.

Helping The Consumer Play Safe



New warning or cautionary statements being required by FDA to advise consumers on proper use of aerosol products and certain cosmetics.

by Harold C. Hopkins

One of the primary legal obligations of the manufacturers and processors of foods, drugs, and cosmetics is to assure that their products are safe for the consumers who purchase them. But many products cannot be made absolutely safe nor can safety be assured without discretion or reasonable care by consumers. To help consumers

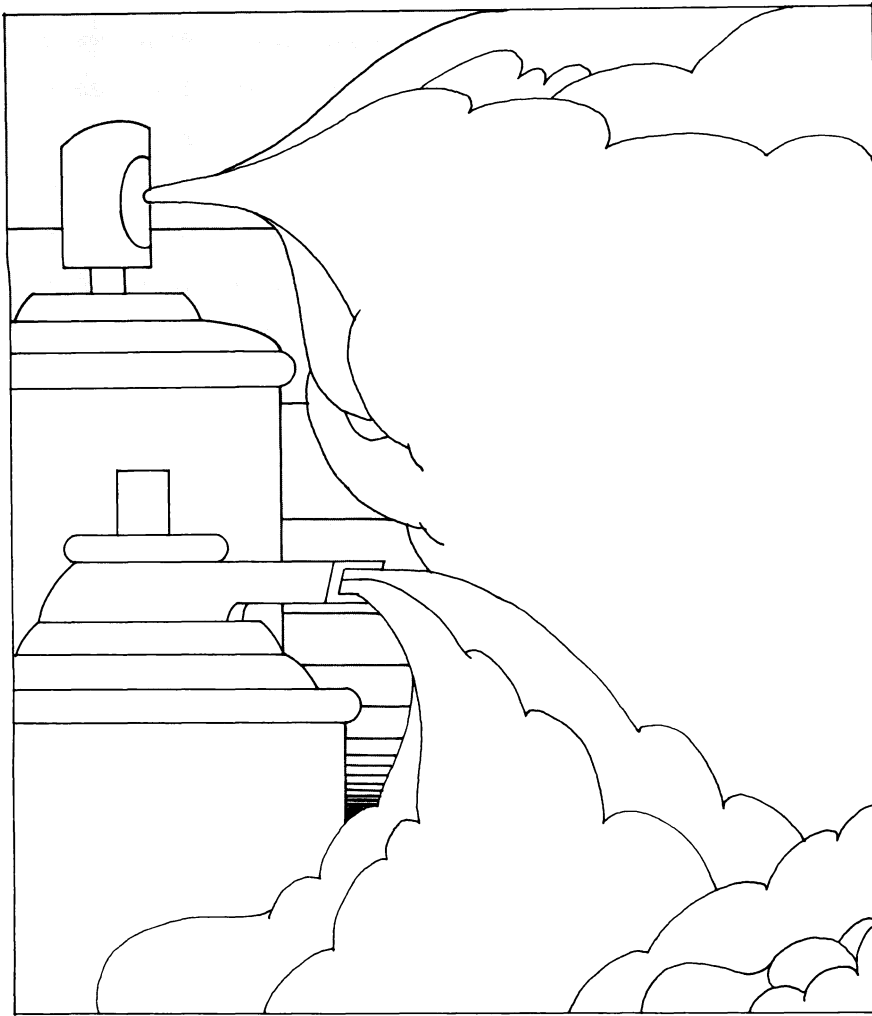
exercise such care and good judgment, FDA has issued new regulations requiring appropriate warning or cautionary statements on three kinds of products: cosmetic feminine deodorant sprays; cosmetics which have not been substantiated for safety by their maker; and foods, drugs, and cosmetics packaged in aerosol (self-pressurized) containers.

The new regulations will require the statements on all applicable labels ordered after March 3, 1976, and on the labels of all such products manufactured after September 3, 1976. No product without the required warning may be introduced into interstate commerce after September 3, 1977.

The requirement for warnings on the labels of foods, drugs, and cosmetics in self-pressurized or aerosol containers provides for two types of statements. The first is a general warning on all self-pressurized containers, with some modifications permitted where applicable. It will say:

"WARNING—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120° F. Keep out of reach of children."

This statement is intended to help consumers protect themselves against injury from explosion of the container and from accidental discharge



into the eyes, where the foreign nature of the product and the force of the entry could be injurious, and where the rapid evaporation of the propellant substance and alcoholic or other carrier substances in the product can produce a chilling or freezing effect that may seriously injure the eye's tender membrane.

For products not expelled as a spray, the part of the warning concerning the eyes may be omitted, since creams or foams, being compact, are not as likely to enter the eye accidentally. Drug products intended for use in the eyes need not carry the eye warning. When a food or cosmetic is intended for use by children, the part of the statement about keeping out of reach of children may be followed by the words "except under adult supervision."

The second type of warning is required, in addition to the first,

for self-pressurized containers in which the agent used to expel the product is partially or wholly a halocarbon or hydrocarbon. Some of these propellants have been responsible for a number of deaths of persons, especially juveniles and adolescents, who deliberately concentrated and inhaled the atomized vapors of various products containing these substances to induce a euphoric effect or "high." According to reports of these cases, the sprays have been concentrated in a number of ways. The most publicized concentration method is spraying the contents of the container into a plastic or other bag. The captured vapor, in high concentration, is then inhaled. In the deaths reported, the precise cause is not always known, but sudden heart arrest and deprivation of oxygen to vital organs such as the brain have

been indicated in several reports.

The required statement will say: "WARNING—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal."

It is intended to be a warning against deliberate rather than accidental misuse, since FDA has received no reports of and does not have any information that injuries or deaths have resulted from normal use of the products involved.

The warning is not required for products expelled in the form of a foam or cream if the halocarbon or hydrocarbon constitutes less than 10 percent of the product; for products whose containers do not permit the escape of the propellant when used; for products of less than 2 ounces net contents in a container designed to release a measured amount of the contents each time the release valve is activated; and for any product with a net content of $\frac{1}{2}$ ounce or less. FDA believes it is unlikely that these products can be misused to cause injury.

FDA rejected one argument that it cannot legally require the warning because the injuries and deaths reported have resulted only from deliberate misuse. Because juveniles and adolescents are involved, the warning is also intended for parents, who can exercise their judgment in taking precautions to prevent misuse of the product by their children.

There is no evidence to indicate that aerosol products containing halocarbons and hydrocarbons are health hazards if properly used, but FDA said more scientific study is needed to determine their safety under conditions of long-term use at low, customary concentration.

A third type of warning applies to all cosmetics, regardless of formulation, container, or packaging, which have not complied with the requirement of the Food, Drug, and Cosmetic Act that a product's safety be adequately substantiated by the manufacturer before it is placed on the market.

The statement will say:

"WARNING—The safety of this product has not been determined."

Adequate substantiation of safety involves animal and human toxicological testing based on the labeled uses of the product as well as "reasonably expected related uses." In substantiating a product's safety, the manufacturer may rely on test data already available on individual ingredients and similar formulations; however, additional tests are always needed for his particular product. FDA mentioned several cosmetic test procedures it regards as "reasonable approaches" to adequate safety evaluation, and noted that where there is scientific controversy, "reasonable scientific opinion" is the criterion. There is no premarket clearance of cosmetics for safety by FDA, and the manufacturer is solely responsible for the safety of his product, FDA noted.

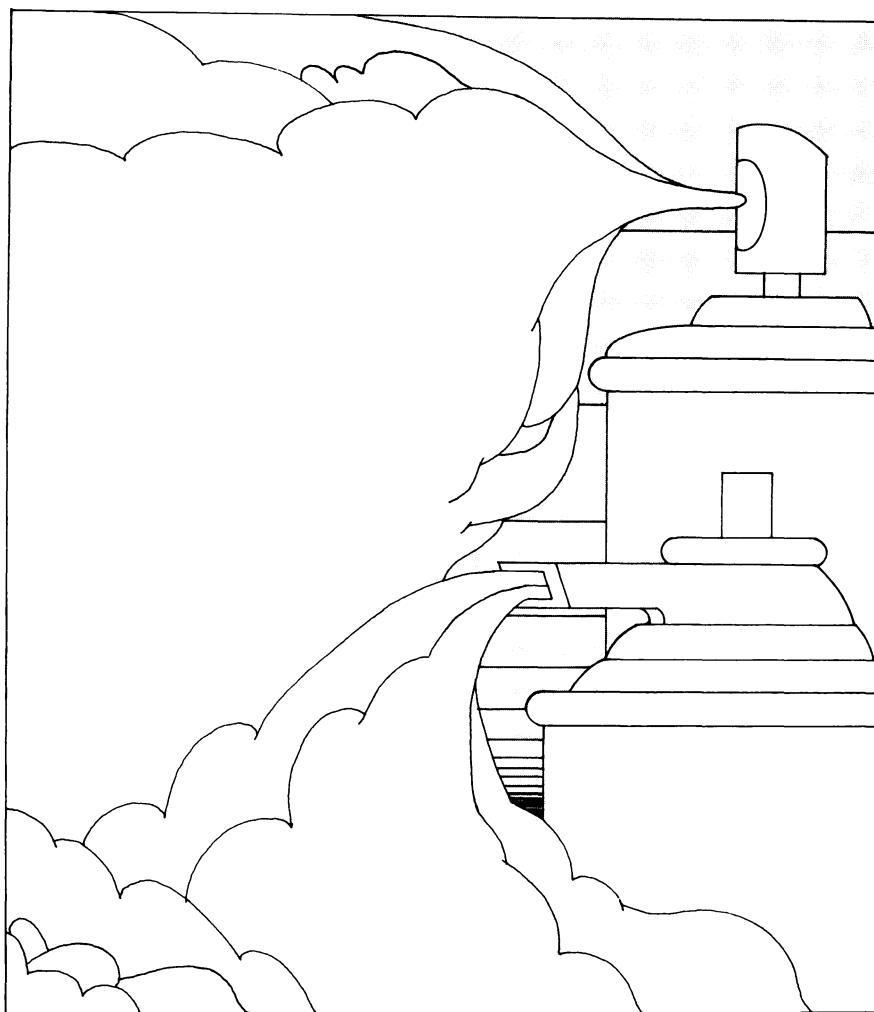
New information that brings into question the safety of an ingredient or product already on the market, unless it is *conclusive*, will not be used by FDA as a basis for requiring the warning statement on the label if the product was adequately tested where it was marketed, if the new information does not demonstrate a hazard to human health, and if studies are undertaken to resolve the safety question posed by the new information as expeditiously as possible.

The cautionary statement for feminine deodorant sprays is required by FDA because of many complaints from both consumers and physicians about adverse reactions such as itching, burning, blistering, and related effects.

The statement will say:

"CAUTION—for external use only. Spray at least 8 inches from skin. Do not apply to broken, irritated, or itching skin. Persistent, unusual odor or discharge may indicate conditions for which a physician should be consulted. Discontinue immediately if rash, irritation, or discomfort develops."

It will be required on the labels of all feminine deodorant sprays, de-



fined to mean any spray deodorant product whose label "represents or suggests" that it is for use in the female genital area "or for use all over the body." The statement is not required on underarm deodorants if the labels do not suggest use on other parts of the body.

When propellants are not expelled with the product—thus not subjecting the sprayed area to possible burn injury from the chilling effect caused by rapid evaporation—the caution to spray at least 8 inches away from the skin may be omitted.

Use of the word "hygiene" or similar words in labeling of feminine deodorant sprays is considered by FDA to be misleading to the consumer, since the Agency feels that these products serve no medical or hygienic purpose. Any suggestion that the product serves such

a purpose renders it misbranded and subject to FDA's drug regulations, which require the manufacturer to prove its safety and efficacy before marketing. FDA will regard feminine deodorant sprays as cosmetics so long as no drug claims are made.

A feminine deodorant spray or any other cosmetic labeled or otherwise represented as a deodorant is a product which is expected to destroy, mask, or neutralize unpleasant body odor when used as directed. FDA will develop a uniform definition of the term "deodorant." Any product claiming to be a deodorant will have to meet the required minimum standards for effectiveness to avoid being considered misbranded.

Harold Hopkins is editorial director of FDA CONSUMER.

Laxatives: What Does 'Regular' Mean?

Advisory Panel says public misconceptions lead to overuse of self-prescribed laxatives. FDA will issue new standards after reviewing comments on Panel's recommendations on acceptable ingredients and labeling claims.

by Charles R. Beek

Television commercials tell us that for good health and well-being we should all be "regular." We needn't be troubled with "irregularity," biliousness, aftermeal discomfort or headaches, if we will take the named laxative. Even Mae West of early film fame attributes the longevity of her good looks to a daily enema.

An independent panel of physicians, pharmacologists, and consultants appointed by FDA to review the safety, effectiveness, and labeling of over-the-counter (OTC) laxatives has found nevertheless that what the public knows about regular or normal bowel functioning still leaves a great deal to be desired. The Advisory Review Panel on OTC Laxatives, Antidiarrheal, Emetic, and Antiemetic Drug Products, said:

"In the United States, preoccupation with the bowel seems to be the concern of a significant proportion of our population judging from the inordinately large number of laxative agents available and by the significant expenditure for OTC laxatives. The Panel is of the opin-

ion that a large segment of the population is not only 'bowel-conscious,' but also has many misconceptions of normal bowel function. The laity is under the impression that serious and health endangering consequences will occur if the bowel is not evacuated daily. The Panel is of the opinion that there is widespread overuse of self-prescribed laxatives. Extensive advertising by the pharmaceutical industry has contributed to this problem."

This report is the first step toward setting definitive Federal standards for OTC laxative, antidiarrheal, emetic, and antiemetic drug products, comparable to those now set for antacids. The final antacid standards, established June 4, 1974, were the first issued as part of the massive class-by-class review launched by FDA in 1972 to evaluate all OTC drugs. (How the review is being conducted was described in "OTC Drug Review: An Update," FDA CONSUMER, May 1974.) The laxative, antidiarrheal, emetic, and antiemetic class is the third of 27 groups of OTC drugs that will be reviewed. It will be several years before final monographs (standards) are issued for all the classes.

When standards are issued for all of them, the consumer will have greater assurance that every OTC drug available is not only safe and effective, but is properly labeled and formulated. Changes in advertising claims, which are regulated by the

Federal Trade Commission, also are likely to result from many of the new standards.

It probably will be sometime in 1976 before the final standards will be issued for laxative, antidiarrheal, antiemetic, and emetic drugs. The report, together with a proposed regulation, was published by FDA as a formal proposal in the March 21 *Federal Register*. This will enable the public as well as the regulated industry to comment on the proposed regulation before FDA takes final action.

After a careful review of all comments submitted by the public, FDA will prepare a proposed final regulation to establish standards for OTC laxative, antidiarrheal, emetic, and antiemetic products. This proposed regulation (called a tentative final monograph) is expected to be issued sometime late this year, but it will not be formally adopted until after all objections have been reviewed by FDA. This process will not be completed until next year.

It is not anticipated that the new laxative, antidiarrheal, emetic, and antiemetic standards, when they become effective, will cause many products to be removed from the market. This is because most firms will limit their labeling and promotion to allowable claims, change their dosage and ingredients to meet the new standards, or perform appropriate safety and effectiveness testing to support claims that require further substantiation.





FDA's final standards will describe conditions under which OTC laxative, antidiarrheal, emetic, and antiemetic products will be recognized as safe and effective and not misbranded. They will include the specific active ingredients, combinations of active ingredients, combination criteria, and labeling statements that will be allowed on marketed products.

Any company that markets an OTC laxative, antidiarrheal, antiemetic, or emetic product will have to use only those ingredients found to be acceptable. Labeling will have to conform to the requirements set forth in the standards. Any company wanting to market a product

that deviates from the standards either will have to petition the Commissioner of Food and Drugs to amend the standards or get approval through FDA's New Drug Application (NDA) procedures.

The Panel's findings on laxative ingredients and labeling in marketed products are set out in three categories:

- Ingredients generally recognized as safe and effective and as not mislabeled. The Panel recommends that ingredients and labeling in this category be included in the final standards.

- Ingredients not generally recognized as safe and effective or which are mislabeled. The Panel

recommends that such ingredients be eliminated or the labeling claims corrected within 6 months after publication of the final standards in the *Federal Register*. This would be required regardless of whether further testing is undertaken to justify their future use.

- Ingredients or labeling claims for which the available data are insufficient to permit final classification at this time. The Panel recommends that ingredients or labeling claims in this category be permitted to remain in use for 2 years after the date of publication of the final standards in the *Federal Register*, if the manufacturer or distributor of any such drug conducts tests and

studies during that period to satisfy the questions raised by the Panel.

Although the Advisory Panel's report does not impose any legal requirements on the pharmaceutical industry at this time, it does provide much useful information for the industry and the consuming public. It can help consumers select the right type of laxative product for a particular indication or problem, and it can help manufacturers determine whether changes may be necessary in formulations or labeling or whether additional supporting data may be required for continued use of questioned ingredients or claims.

The Panel took issue with a number of advertising claims that often are heard in connection with laxatives. "Any statement that suggests a laxative is somehow 'natural' because of its source is misleading," the Panel said, "because it implies that the product or ingredient is a 'natural way' to induce laxation. It is not considered natural to take any laxative."

"Irregularity" as an indication for use of laxatives also is misleading, the Panel said, because "regularity" of bowel movement is not essential to health or well-being. Variability of frequency of bowel movements is normal within certain limits, the Panel found. Based on two recent studies, normal limits for bowel habits were suggested. In one study of 1,055 industrial workers (655 women and 400 men) in the London area, it was found that bowel movements ranging from three a week to three a day can be normal. In the other study, involving 115 healthy adult men in a U.S. Federal correction institution, the interval between stools varied from 9 to 57 hours.

The Panel said that the bowel habits of many laxative users seem to fall within the normal range, and these people apparently have no physical or organic condition requiring the use of laxatives. Simple constipation most often results from improper diet, inadequate fluid in-

take, insufficient exercise, or a change of habits due to travel, the Panel said. There are only a few valid indications for the use of laxatives, according to the Panel, and "relief for simple constipation often may be achieved by proper diet, including foods with adequate fiber content, adequate fluid intake, and the prompt response to the urge to evacuate the bowels."

The Panel has recommended a number of specific changes in current labeling so consumers can compare products and get a better understanding of how they work. This would enable consumers to avoid products containing ingredients they should not take. For example, the Panel has recommended that all laxative labels state that the product should be used only "for the short-term relief of constipation." To help the consumer know what to expect from taking the product, the Panel recommended that the labels also include the specific mode by which the product acts to relieve constipation: "To increase frequency of bowel movements," "To soften stool," or "To increase bulk of the stool."

The Panel also has called for a label warning to consumers on products containing relatively high amounts of sodium. It recommends requiring a sodium statement of content per dosage unit where sodium exceeds 23 milligrams per maximum daily dose. If sodium exceeds 345 milligrams per daily dose, the Panel said, the label should warn against use of the product by people on a low salt diet or by those who have kidney disease "except under the advice and supervision of a physician."

For stimulant-type laxatives, the Panel suggests the following label warning: "Prolonged or continued use of this product can lead to laxative dependency and loss of normal bowel function. Serious side effects from prolonged use or overdose can occur. This product should be used only occasionally, but, in any event no longer than daily

for 1 week, except on the advice of a physician."

Castor oil, a long-familiar laxative ingredient, should be taken infrequently and then only as a one-time, single dose, the Panel warned.

The Panel divided laxatives into broad categories, based on how they are supposed to work. The categories and modes of action are:

- Bulk-forming laxative: Promotes evacuation of the bowel by increasing bulk volume and water content of the stools.

- Stimulant laxative: Promotes bowel movement by one or more direct actions on the intestine.

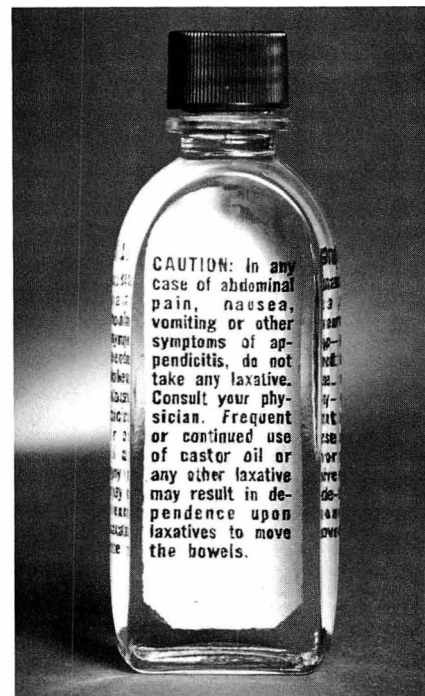
- Hyperosmotic and saline laxatives: The hyperosmotic agent attracts water into the stool. The saline agent increases water in the intestine, thereby promoting bowel movement.

- Lubricant and stool softener laxatives: Lubricant agents lubricate the contents of the intestinal tract, promoting easier bowel movements. Stool softeners penetrate and soften the stool.

For all of these laxative categories, the Panel has recommended only 25 acceptable ingredients, or groups of ingredients, as proved safe and effective.

Six of these ingredients are used in bulk-forming laxatives, which the Panel found are among the safest of laxatives. Bulk-forming laxatives generally are not absorbed from the digestive tract and therefore would have less possibility of causing any adverse side effects, the Panel pointed out. It also noted, however, that most of these laxatives should be taken with a full glass of liquid to minimize the risk of digestive tract obstruction.

Eight stimulant-type laxative ingredients were found safe and effective, but the Panel cautioned that this type of laxative should be used only occasionally. It is possible for an ingredient to be found generally safe and effective, while specific labeling claims made in its behalf are questionable. This was the case with dehydrocholic acid. The Panel



The Advisory Panel recommended that all laxative labels, regardless of the type or form of the laxative, state that the product should be used only "for short-term relief of constipation." Castor oil, a long-familiar laxative, should be taken infrequently, the Panel advised, and then only as a one-time, single dose. The caution label now carried on a bottle of castor oil is shown above.

approved it as a stimulant-type laxative ingredient, but found unacceptable the claims that it relieves "indigestion," "excessive belching," "aftermeal discomfort," or "the sensation of abdominal fullness."

Four saline and two hyperosmotic laxative ingredients were found safe and effective. The Panel recommended that saline laxatives be restricted to occasional use, because serious saline imbalances have been reported with their long-term daily use. It also urged that products containing glycerin—one of the two acceptable hyperosmotic ingredients—should state: Glycerin administered rectally may produce in some individuals rectal discomfort or a burning sensation."

Two lubricant ingredients, plain mineral oil and emulsified mineral oil, and three stool softener ingredients were considered acceptable by the Panel. The Panel concluded that these products as well as all laxatives should not be used for a period longer than 1 week except under the advice and supervision of a physician.

Mineral oil preparations would be required to have a warning against use in conjunction with a stool softener. In addition, plain mineral oil would be labeled for use only at bedtime and not for use in certain individuals—including infants, pregnant women, and bed-

ridden or aged patients—except under advice and supervision of a physician. Emulsified mineral oil would be labeled for divided doses, the first dose on rising and the second dose taken only at bedtime and neither dose at mealtimes.

The Panel also found that dioctyl sulfosuccinate preparations (one form of the acceptable stool softener) might increase the potency of other drugs being taken and recommended that the label should state: "Drug interaction precaution: Do not take this product if you are presently taking a prescription drug or mineral oil." The Panel also concluded that rectal suppositories which release carbon dioxide

FDA's latest survey of pesticides in food shows a slight overall drop from levels recorded in the 1960's. The lower level of DDT apparently reflects the sharp curtailment of its use on crops.

Drastic curtailment of the use of DDT on crops and elsewhere appears to have resulted in a decline in DDT-related pesticides in the Nation's food supply, according to an FDA survey.

The decline was noted in all the food products surveyed except eggs, where DDT residues remained constant, and fluid whole milk, where there was a slight increase. The DDT product found in milk, a degraded form known as DDE, has remained in the environment and may be expected to show up in other foods of animal origin, particularly fish.

The information on DDT comes from a study made by FDA in fiscal year 1973 of pesticide residues in foods. Results of the study indicate there was a slight overall decline in residues from the levels found in a study covering the years 1963-69, but statistically valid comparisons are precluded by differences in the size and design of the two surveys.

The new survey was conducted by FDA for residues of pesticides and PCB's (polychlorinated biphenyls, a class of toxic industrial chemicals) found in 10 major food categories. PCB's were not known to present a health hazard during the 1960's and were not included in the earlier study. The new study does not encompass findings by the U.S. Department of Agriculture of pesticide residues in meat and poultry as did the earlier study, although FDA will work toward incorporating these data in future publications of combined results.

Generally, pesticide residue violations fall into one of two categories. For some pesticides, maximum levels—amounts which can be tolerated in food without posing a health hazard—have been estab-

lished. Residues in excess of these levels are not permitted. For other pesticides, any evidence of the substance in food is considered a violation.

The fiscal 1973 study of violative residues involved 8,388 samples of which 3,013 were imports. It covered raw agricultural products, manufactured dairy products, shell eggs and egg products, fish, processed animal feeds, vegetable oils, fluid whole milk, processed foods, foods for special dietary use, treated seeds, and a few other miscellaneous categories. Permitted pesticide residue levels or prohibited residues are established by the Environmental Protection Agency, and FDA enforces these tolerances and conducts surveillance to assure that the food supply is free of unsafe residues. FDA takes regulatory action against violations, or in some instances, the States take follow-up regulatory action.

For chlorinated pesticides, the samples showed overall violative residues on or in 2.1 percent of domestic products and 1.8 percent of imported products and, for organophosphorus pesticides, 1.1 percent of domestic products and 3.5 percent of imported products.

The survey consisted of sampling of specific food commodities by each FDA District. Where pesticide residues problems were indicated by initial sampling or by other intelligence, selective follow-up sampling was made, and the results were incorporated into the study.

The study made limited use, for the first time by FDA, of a newly developed laboratory detection method capable of detecting up to 60 different organophosphorus compounds or breakdowns (metabolites) of these compounds. The greater part of the study involved use of an older method which can detect about 20 parent organophosphorus compounds but does not detect metabolites of such compounds. FDA intends to increase use of the newer, more comprehensive method in future studies, as resources permit.

One reassuring note to FDA was that in the assays employing the new method, no trace at all was found of some 20 compounds the method is known to detect. In the past, there was no way of knowing whether some of these compounds could be in the food supply, since the older method was incapable of detecting them. Several compounds that were found in foods by use of the new method would have gone undetected if the older method had been used in the tests involved.

The relative frequency of dieldrin residue occurrence declined slightly in raw agricultural products but increased slightly in dairy products, eggs, and fish.

PCB residues were not among those most frequently found except in fish, where their frequency ratio was exceeded only by the DDT-related residues. No comparison figures are available on PCB's for the 1963-69 period.

Organophosphorus pesticide residue occurrence was not significant in dairy products, eggs, and fish, but a slight shift toward more residues in raw agricultural products appears to be developing, possibly as the result of the shift away from use of the organochlorine pesticides, which are stable and persistent and remain longer in the environment, to the phosphated pesticides, which are less persistent in the environment.

Combined endosulfan compounds, toxaphene, and carbaryl appear to have increased in relative frequency. BHC (benzene hexachloride) occurrence increased in domestic milk, dairy products, and fish, and remains the most frequently encountered residue in imported (European) cheese.

Copies of the FDA survey, "FY 1973 Pesticide/PCB in Foods Program—Evaluation Report," are available without charge from the Assistant Commissioner for Professional and Consumer Programs (HFG-1), Food and Drug Administration, Room 15B-41, 5600 Fishers Lane, Rockville, Maryland 20852.

FDA Consumer / May 1975 / 23

contains no artificial flavors or colors. This statement, however, cannot imply that such ingredients are dangerous.

Halt Ordered in Use of Dental Device

The FDA has ordered the manufacturer of the "Nuva-Lite Activator Light," a dental appliance, to notify all owners and users to discontinue use until ultraviolet (UV) radiation leakage from the device can be corrected. In a meeting with FDA officials, the manufacturer, the L. D. Caulk Co., also agreed to stop temporarily, all distribution and sales of the device.

According to FDA's Bureau of Radiological Health, the UV light-producing device, used for hardening restorative plastic applied to teeth, poses a health hazard to dental personnel and to patients. UV radiation can cause burns to exposed skin and to eye tis-

cles for carbonated beverages and beer. The Agency is seeking the broadest possible public comment on the action from consumer and environmental groups, industry representatives, professional organizations, Federal and State agencies and individuals.

The environmental statement was prepared because the FDA received a number of food additive petitions requesting amendment of its regulations to permit the use of plastic bottles with gas barrier properties. These bottles are designed to prevent the escape of carbon dioxide and thus maintain the carbonation of soft drinks and beer. The National Environmental Policy Act of 1969 requires that an Environmental Impact Statement be prepared for all major Federal actions that might significantly affect the quality of the human environment.

While its statement on plastic bottles unequivocally supports findings of adverse impact on the environment

News Highlights

Court Bars Shipment of Laetrile

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The products, Aprikern and B17, are manufactured as capsules and as a food supplement by General Research Labs, Inc., of Van Nuys, California. The U.S. District Court in Los Angeles ruled on April 25 that both products were intended for use in the "cure, mitigation, treatment and prevention of cancer and [were] thus drugs."

Both Aprikern and B17 contain amygdalin, another name for Laetrile, the controversial cancer drug that has never been shown to have any effect on that disease.

The court said official corporate bulletins and letters sent out by General Research Labs made it clear that the company intended Aprikern and B17 to be substitutes for Laetrile injections in treating, preventing, and curing cancer. Laetrile injections are illegal in the United States.

Based on analytical work done by the University of Arizona and FDA, the court also found that Aprikern

- Apricot fruit-and-kernel concentrate containing 500 milligrams of amygdalin was of special nutritive value in human nutrition.

The court found these claims false and misleading because there is no scientific evidence to support them.

The injunction prohibits the defendants from shipping these two products and any similar product in interstate commerce.

Sharp to Correct Hazard in TV Sets

Sharp color television sets that could emit potentially dangerous radiation will be repaired at no cost to set owners, under a corrective action program submitted by the company and approved by FDA.

FDA tests indicate that failure of a certain component in the Sharp 15-inch television receiver—model C-1541—could cause the set to emit radiation in excess of that permitted by the Federal standard. Should the component fail, the set still may appear to function normally while emitting radiation in excess of the standard.

Less than 2,000 units of model C-1541 are believed to be in consumer hands in the United States.

Regional Reports

REGION I

The Federal Government seized some 4,000 pounds of brie and camembert cheese at East Boston, Massachusetts, after examination by FDA's **Boston Field Office** found it decomposed. The cheese had been imported from France, but it was not definitely established when and where decomposition occurred. The cheese was destroyed at a local dump after the U.S. District Court at Boston entered a default decree condemning it.

In a judgment resulting from an investigation by FDA's Boston Field Office, Ace Baking Co., Inc., Roxbury, Massachusetts, and company officials Leo Feldman and Arthur Feldman were found guilty of adulterating foodstuffs and were fined a total of \$900 by Judge Joseph Tauro in U.S. District Court at Boston. The Government charged the defendants with allowing foods to become adulterated by insects and with storing foods under insanitary conditions whereby they may have become contaminated by filth. The defendants had pleaded not guilty at arraignment, but later changed their pleas to nolo contendere on two counts. The corporation pleaded guilty to two counts. Four additional counts against the defendants were dismissed.

REGION II

Import inspectors at FDA's **Buffalo District** detained

led to Lipton's recall of the product and to Alfonso Gioia & Sons' recall of several other noodle products under the latter's own brand as well as to recall another company's product containing noodles made by the Rochester firm.

Inspectors from FDA's **New York District** found live mice in a dining car in the Sunnyside Rail Yards, where an Amtrak train was being made up for the run from New York City to Kansas City. The diner was removed from service to be fumigated, a replacement car was sent up from Philadelphia, and Amtrak indicated that greater care would be taken in the future to prevent such incidents. FDA has jurisdiction over food, beverages, and water served on interstate carriers, under the Interstate Travel Sanitation Program.

U.S. marshals made a mass seizure of 49 lots of bulk spices at Transit Trading Corp., New York City, when New York District inspectors found them exposed to contamination by filth. The eight-story warehouse was repaired; the spices reconditioned, with \$30,400 worth required to be destroyed; and the contents released floor by floor as the operation was brought into compliance. The New York District monitored the repairs and reconditioning, billing the owner for time and travel.

REGION III

FDA's latest survey of pesticides in food shows a slight overall drop from levels recorded in the 1960's. The lower level of DDT apparently reflects the sharp curtailment of its use on crops.

Drastic curtailment of the use of DDT on crops and elsewhere appears to have resulted in a decline in DDT-related pesticides in the Nation's food supply, according to an FDA survey.

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The court said official corporate bulletins and letters sent out by General Research Labs made it clear that the company intended Aprikern and B17 to be substitutes for Laetrile injections in treating, preventing, and curing cancer. Laetrile injections are illegal in the United States.

Based on analytical work done by the University of Arizona and FDA, the court also found that Aprikern was unfit for food because it contains hydrogen cyanide, a universally recognized poison. The Aprikern label bears no directions for use, the court said, and the chances of accidental poisoning by adults taking as few as ten capsules and children taking as few as two to five are significant.

The court held that even if Aprikern and B17 were intended for use only as food, they would require approval by FDA before marketing because they contain amygdalin, which has not been proven safe for use in food. The court held that amygdalin is a food additive as defined in the Food, Drug, and Cosmetic Act and that there is no regulation in effect permitting its use in food nor exempting it from the food-additive requirements.

Finally, the court held that the label of B17 was false and misleading because it represented that:

- The product was vitamin B₁₇.
- Vitamin B₁₇ is recognized as an essential nutrient in human nutrition.
- Vitamin B₁₇ is a member of the B complex family of vitamins.

- Apricot fruit-and-kernel concentrate containing 500 milligrams of amygdalin was of special nutritive value in human nutrition.

The court found these claims false and misleading because there is no scientific evidence to support them.

The injunction prohibits the defendants from shipping these two products and any similar product in interstate commerce.

Sharp to Correct Hazard in TV Sets

Sharp color television sets that could emit potentially dangerous radiation will be repaired at no cost to set owners, under a corrective action program submitted by the company and approved by FDA.

FDA tests indicate that failure of a certain component in the Sharp 15-inch television receiver—model C-1541—could cause the set to emit radiation in excess of that permitted by the Federal standard. Should the component fail, the set still may appear to function normally while emitting radiation in excess of the standard.

Less than 2,000 units of model C-1541 are believed to be in consumer hands in the United States.

Pending correction of the sets, the distributors, Sharp Electronics Corporation, of Paramus, New Jersey, has agreed to stop further distribution and delivery of the substandard model and to compile a list of owners. The sets are manufactured in Japan.

In January of this year, FDA ordered corrections in more than 400,000 TV sets manufactured by the Matsushita Electric Corporation, and in March, ordered corrections in 5,000 Quasar (not to be confused with the name formerly used by Motorola) and Toshiba TV sets. Corrective programs are now underway. The problem in these earlier cases was similar to that now indicated in the Sharp receivers.

Data Sought on Additives, Hyperactivity

FDA is encouraging studies to develop the kind of information it believes is needed to determine the validity of a widely-publicized theory that artificial food flavors and colors cause hyperactivity in children.

One such study is underway at the Food Research Institute at the University of Wisconsin. When com-

pleted, this study should assist FDA in getting the answers needed to minimize adverse reactions to food. In related efforts, FDA has allocated \$250,000 in fiscal year 1976 for studies designed to develop information on human intolerance to food additives.

The theory that food additives are related to hyperactivity in children has been advanced primarily by Dr. Benjamin Feingold, chief emeritus of the Kaiser Permanente Medical Center Allergy Department. FDA does not discount Dr. Feingold's thesis, but definitive scientific evidence is required before the Agency can take action. FDA has pointed out that its scientists do not know of any completed carefully controlled studies which relate hyperactive behavior in children to ingestion of food or color additives. To date, Dr. Feingold has not provided FDA with the kinds of data demanded by both science and the law to substantiate his observations.

Dr. Feingold is in favor of all appropriate food labels having a prominent symbol showing they contain no artificial colors or flavors. FDA has no objections to any food label which emphasizes that the product contains no artificial flavors or colors. This statement, however, cannot imply that such ingredients are dangerous.

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The FDA has ordered the manufacturer of the "Nuva-Lite Activator Light," a dental appliance, to notify all owners and users to discontinue use until ultraviolet (UV) radiation leakage from the device can be corrected. In a meeting with FDA officials, the manufacturer, the L. D. Caulk Co., also agreed to stop temporarily, all distribution and sales of the device.

According to FDA's Bureau of Radiological Health, the UV light-producing device, used for hardening restorative plastic applied to teeth, poses a health hazard to dental personnel and to patients. UV radiation can cause burns to exposed skin and to eye tissue.

FDA estimates there have been about 25,000 Nuva-Lite appliances sold in the United States.

FDA first became aware of a defect with this device as a result of information provided through its radiation incidence registry system. Subsequent investigation, including inspection of the manufacturer's plant, indicated that the problem was limited in nature. As a result, FDA approved a plan in March of this year allowing the company to modify defective units by sending corrective parts to owners with instructions on how to attach them to the appliance.

Findings of additional leakage problems, however, caused FDA to direct the manufacturer to notify owners of the device to stop using it. Also, while inspecting company quality control records, FDA found at least 31 unreported cases of suspected or confirmed injury that are required by law to be reported to the

Agency. The cases included eye irritations and minor burns to face and lips.

In addition to ordering that the company advise non-use of the light pending correction, FDA is requiring Caulk to: (1) submit a revised corrective action plan for eliminating newly discovered sources of UV radiation leakage or replacing the product or refunding its cost; (2) have all repairs made at the factory or by factory representatives; and, (3) stop all sales and distribution until corrective action plans can be approved and the units repaired.

The company has sent a certified letter—approved by FDA—explaining the problem to the 19,600 known purchasers and is trying to locate and contact additional purchasers. FDA has asked the assistance of the American Dental Association in reaching all possible users of the light.

FDA Issues Report on Plastic Bottles

The Food and Drug Administration has prepared a draft Environmental Impact Statement on plastic bottles for carbonated beverages and beer. The Agency is seeking the broadest possible public comment on the action from consumer and environmental groups, industry representatives, professional organizations, Federal and State agencies and individuals.

The environmental statement was prepared because the FDA received a number of food additive petitions requesting amendment of its regulations to permit the use of plastic bottles with gas barrier properties. These bottles are designed to prevent the escape of carbon dioxide and thus maintain the carbonation of soft drinks and beer. The National Environmental Policy Act of 1969 requires that an Environmental Impact Statement be prepared for all major Federal actions that might significantly affect the quality of the human environment.

While its statement on plastic bottles unequivocally supports findings of adverse impact on the environment through use of such containers, FDA concludes that it has legal authority to take action against such containers only if there is a question of human health or safety, such as leaching of a harmful chemical from the plastic into the beverage.

"The Food, Drug, and Cosmetic Act does not include authority for FDA to act against a product solely on the basis that it litters the environment," said Commissioner of Food and Drugs Alexander M. Schmidt.

The Commissioner said that FDA's environmental statement on plastic bottles is designed deliberately to spell out the legal dilemma in this and similar situations and to stimulate public debate which may lead to resolution either in the courts or in the Congress.

"For the Agency to take a position other than it has taken would be an arbitrary and challengeable assumption of authority," said the Commissioner.

Regional Reports

REGION I

The Federal Government seized some 4,000 pounds of brie and camembert cheese at East Boston, Massachusetts, after examination by FDA's **Boston Field Office** found it decomposed. The cheese had been imported from France, but it was not definitely established when and where decomposition occurred. The cheese was destroyed at a local dump after the U.S. District Court at Boston entered a default decree condemning it.

In a judgment resulting from an investigation by FDA's Boston Field Office, Ace Baking Co., Inc., Roxbury, Massachusetts, and company officials Leo Feldman and Arthur Feldman were found guilty of adulterating foodstuffs and were fined a total of \$900 by Judge Joseph Tauro in U.S. District Court at Boston. The Government charged the defendants with allowing foods to become adulterated by insects and with storing foods under insanitary conditions whereby they may have become contaminated by filth. The defendants had pleaded not guilty at arraignment, but later changed their pleas to *nolo contendere* on two counts. The corporation pleaded guilty to two counts. Four additional counts against the defendants were dismissed.

REGION II

Import inspectors at FDA's **Buffalo District** detained a 1,040-case shipment of mixes for the drink "Bloody Mary," valued at \$6,219 and offered for import from Canada at Buffalo, because the containers were damaged, rendering the product unfit for consumption.

Staff members of the Buffalo District were prepared to give evidence in a \$3 million damage suit by Thomas J. Lipton, Inc., Auburn, New York, against Alfonso Gioia & Sons, Inc., Rochester, New York, when the case was settled out of court for \$825,000. Lipton sued after the Buffalo District had found in 1970, during routine collection and analysis of samples of Lipton's Chicken Noodle Dry Soup Mix, that the product was contaminated with *Salmonella* bacteria and the FDA finding was verified by Lipton. Lipton then found, and FDA investigated and verified, that the source of the *Salmonella* was noodles supplied to Lipton by Alfonso Gioia & Sons. These findings

led to Lipton's recall of the product and to Alfonso Gioia & Sons' recall of several other noodle products under the latter's own brand as well as to recall another company's product containing noodles made by the Rochester firm.

Inspectors from FDA's **New York District** found live mice in a dining car in the Sunnyside Rail Yards, where an Amtrak train was being made up for the run from New York City to Kansas City. The diner was removed from service to be fumigated, a replacement car was sent up from Philadelphia, and Amtrak indicated that greater care would be taken in the future to prevent such incidents. FDA has jurisdiction over food, beverages, and water served on interstate carriers, under the Interstate Travel Sanitation Program.

U.S. marshals made a mass seizure of 49 lots of bulk spices at Transit Trading Corp., New York City, when New York District inspectors found them exposed to contamination by filth. The eight-story warehouse was repaired; the spices reconditioned, with \$30,400 worth required to be destroyed; and the contents released floor by floor as the operation was brought into compliance. The New York District monitored the repairs and reconditioning, billing the owner for time and travel.

REGION III

A default decree of condemnation, signed in the Eastern District of Pennsylvania by Judge Edward R. Becker, led to destruction of 348,250 capsules of various amphetamine combination drugs. The drugs, which are illegal under Federal law, had been seized in the offices of Dr. Henry J. Glah of Lancaster in August 1974, and their status had been in litigation until early this year. Once that status was resolved, they were destroyed by burial in a landfill. FDA and the Drug Enforcement Administration of the Department of Justice cooperated in the seizure and subsequent destruction.

A supply of illegal drugs (180,000 10 mg tablets) in the possession of Dr. Howard T. Lewis, Jr., of Pittsburgh, was voluntarily destroyed under supervision of the Federal Drug Enforcement Administration (DEA), the agency concerned with drugs of abuse.

FDA's **Pittsburgh Resident Post** had inspected the drugs at the request of DEA, and found amphetamines labeled as appetite depressants (for weight reduction), a use no longer permitted, and amphetamines combined with barbiturates (amobarbita), a drug combination not approved for sale, prescription, or use. Records showed the drugs had been purchased in 1968, 1971, and 1973, and were still being dispensed and prescribed.

During the 1960's drug manufacturers marketed and many physicians prescribed these drugs as diet pills. Their use as diet pills dropped sharply in the late 1960's after FDA studies showed the drugs were not effective for this purpose, and that they can create a drug dependency problem for the users. Amphetamines are now more strictly controlled as drugs of high abuse potential; their manufacture has been cut back 90 percent since 1971; and labeling them for weight reduction or having them in combination with other active ingredients is prohibited.

REGION IV

The Government made a mass seizure of foods valued at \$50,000 because of insanitary conditions and live insect infestation at a wholesale warehouse, Reina Brothers, Inc., at Tampa, Florida, after repeated inspections between January 1969, and October 1974, disclosed insect and vermin activity throughout. The seized products, including flour, cracker meal, nuts, peas, beans, corn muffin mix, and pet foods, had been placed under a stop-sale order by the Florida Department of Agriculture pending the seizure action, based on inspection and collection of samples by Consumer Safety Officer Larry Swindal of FDA's **Orlando District**. About 18,300 pounds of the food was destroyed and the remainder reconditioned under the terms of a consent decree of condemnation which also required clean-up of the warehouse.

Orlando District Consumer Safety Officer Mary Action, while making import examinations in Jacksonville, Florida, discovered that three lots of green coffee offered for import from Brazil contained moldy beans and insects. The coffee, 665,000 pounds valued at \$330,000, was detained.

During one week the Orlando District made ten import detentions of products with a total value of \$3,581, as follows: bamboo shoots from Hong Kong whose labels did not meet technical requirements of the Fair Packaging and Labeling Act (FPLA); breakfast cereal from Colombia with no English language labeling; orange juice, grapefruit juice, carrot juice, and orange marmalade, all from Jamaica and whose labels failed to meet technical requirements of the FPLA; x-ray units from Japan which did not disclose the date of manufacture as required on labeling; two lots from

Spain of the so-called youth drug, KH-3, which does not have an FDA-approved New Drug Application; and a lot of Wobe Mucos Micro brand enemas from Germany without English language labeling.

Lloyd McEwen and Alan Moore, Region IV consumer safety officers of FDA's **Charlotte and Raleigh Resident Posts**, respectively, in North Carolina, monitored the destruction, at Charlotte and Raleigh, of 27,784 cans of oysters, valued at \$17,689, that had been imported from Korea and were recalled when FDA inspection and sampling found they were under-processed.

A half hour after a tornado struck Atlanta on March 24, causing about \$80 million in damages to industrial and residential areas, FDA's **Atlanta District** inspectors were in the area making inspectional surveys and found that 12 food handling establishments had sustained extensive damage to buildings and contents. The Pepsi Cola Bottling Co. of Atlanta estimated losses of \$3.5 million. Other companies with damage included a tea processor, baking supply warehouse, poultry processor, pet food manufacturer, popcorn supplier, beer and liquor suppliers, a catering service, and a dental supplier. Damage was all caused by water. Some salvage was conducted under supervision of the Georgia Department of Agriculture. Many companies voluntarily destroyed damaged products under FDA monitoring.

A Tennessee drug manufacturer has consented without trial to entry of an injunction which enjoins the company from manufacturing drugs until it manufactures its products in compliance with FDA's regulations on Good Manufacturing Practices. The injunction was entered by Judge Frank Gray, Jr., of the U.S. District Court of the Middle Tennessee District, Nashville Division, against International Drug Co., Inc., Smyrna, Tennessee, also known as Carroll Chemical Co. The case resulted from a series of inspections beginning in May 1973 by FDA's **Nashville District** and charges of gross deviations from Good Manufacturing Practices and the presence of foreign substances in, cross-contamination of, and variations in potency of drugs made by the company, and followed several FDA warnings to the company. Judge Gray said the injunction would remain in effect until dissolved by agreement between the company and FDA.

REGION V

Kroger Company, a supermarket chain, was fined a total of \$50,000 and two of its officers \$1,000 each by Judge Thomas D. Lambros in the U.S. District Court sitting at Cleveland, on charges of storing rodent-contaminated bags of flour and noodles at the company's warehouse at Solon, Ohio, and of shipping the foods for sale in interstate commerce.

The trial followed inspection of the warehouse, laboratory analyses, and preparation of the case by FDA's **Cincinnati District**. The company was fined \$10,000 on each of five counts after pleading guilty, and was given 120 days to clean up the warehouse, at which time Judge Lambros will consider reducing the fine. Lyle Everingham, president of Kroger Food Stores Division, and Newton Briggs, vice president of the company's Cleveland Division, pleaded no contest to one count each, and the fines were suspended.

The Cincinnati District, through the Greater Cincinnati Explorer Scout Council, has established an Explorer Scout post. The members are 11 high school students from the greater Cincinnati area who are interested in scientific careers in chemistry or biology. The post's objective is to provide the students on-the-job experiences in their areas of interest, affording them a better opportunity to understand the types of employment involved when a scientific education is pursued. A side benefit is FDA's opportunity to educate students, their families, teachers, and friends in the scientific and investigational activities of the Agency.

The students have been involved in analyses of aspirin tablets, using a spectrophotometer, and of color in foods using thin layer chromatography.

District Laboratory Director John Feldman is the principal organizer and advisor to the post. Counselors and program coordinators are David Winters, laboratory coordinator; Ray Wesselman, Richard Meier, and Richard Carr, analysts; and Richard Koesinger and Lloyd Besston, investigators.

FDA's **Detroit District** reports a new craze in the Detroit Metropolitan area concerning the candy product, "Pop Rock," manufactured and sold in Canada. When dissolved in the mouth, the candy releases a torrent of carbon dioxide bubbles. An elementary school teacher reported to the District that the sound of the effervescence causes distraction and disturbance in the classroom. Commercial importations have been denied by FDA because the product lacks mandatory label information, such as the name and address of the manufacturer. However, it is reported that large amounts are purchased in Canada by individuals crossing the border, and that school children have paid as high as \$1.00 for a 15-cent package.

REGION VI

A legal footnote in the history of Laetrile, the unproved cancer remedy, was written in mid-March in the U.S. District Court for Western Oklahoma. Laetrile has been identified as amygdalin, a chemical found in the seeds of many plants (apricots, peaches, apples) and which may break down into cyanide, a potent poison. Laetrile has not been approved by FDA as a

safe and effective drug, as required by law, and it may not be shipped within the United States for use on humans.

A woman patient in Oklahoma had obtained some Laetrile from California, and requested that her own physician administer it to her, which he declined to do. The woman then filed suit against the Government, claiming in effect that FDA had no authority to restrict the use of Laetrile; that freedom of choice of treatment and protection against invasion of a patient's privacy were guaranteed by the Fifth and Fourteenth Amendments to the Constitution.

After hearing arguments for the plaintiff and the Government, the court dismissed the suit, saying that it had no basis in law.

Arrow Industries of Carrollton, Texas, a large-scale dry packer of beans and similar produce, signed a consent decree of injunction in the U.S. District Court, Northern District of Texas, and closed for one week while insect infestation throughout the plant was brought under control. FDA's **Dallas District** sought the injunction after finding insects in hoppers, chutes, conveyors, and other equipment. The company spent \$30,000 correcting the problem, and resumed operation after FDA inspection showed that insect activity had been eliminated.

The Dallas District helped a pharmacist and a woman patient locate a long-term supply of sodium heparin which the patient, who had suffered a stroke, required for daily self-injection. Local hospitals could not dispense the drug from their pharmacies, and other suppliers had very little in stock. The Dallas office reached the manufacturer in California, and a three-month supply was sent immediately to the patient's pharmacist.

REGION VII

Voluntary destruction of 1,000 pounds of homeopathic drug products, valued at \$10,000, was carried out by Manola Co., St. Louis, after a routine inspection by FDA's **Kansas City Field Office** of this manufacturer and laboratory analysis revealed insect infestation in the drugs.

In an unusual case in which investigation by FDA's Kansas City Field Office found that Fleming Co., St. Louis, was promoting and distributing diphenylhydantoin capsules, a drug for human use, for veterinary use without an FDA-approved New Animal Drug Application, the Government seized several lots of the product, valued at \$5,400. The action ensued from the Field Office's inspection of the company. Although FDA had warned the company to discontinue the practice, it had continued distributing the product to veterinarians.

Notification by FDA's **Chicago District** to the Kansas City Field Office that orotic acid, an unapproved food additive, was being used in dietary supplement tablets distributed by Private Formulae, Inc., St. Louis, resulted in an investigation and subsequent Government seizure of \$2,300 worth of the additive.

FDA's Kansas City Field Office personnel, in cooperation with Iowa, Kansas, Missouri, and Nebraska soft drink associations, held a sanitation workshop in Kansas City for the soft drink industry. About 160 people attended from the industry, including corporate officials. The program was designed to help correct mold problems and insanitary conditions in the beverage industry. Topics included industry's legal responsibility, consumer complaints, FDA inspections, and laboratory examination of soft drinks.

REGION VIII

The use by a Colorado food processor of sodium nitrate and sodium nitrite in processed pheasant and quail, not permitted by FDA in these foods, has resulted in a city-county embargo of one lot, Federal Government seizure of another, and the company's voluntary withholding of other quantities from the market. The labels of the products indicated content of the two additives.

At the request of FDA's **Denver District**, the City-County Health Department of Colorado Springs embargoed 333 three-pound cans of smoked pheasant at the processing plant, High Valley Farm, at that city, pending the outcome of FDA's complaint for forfeiture filed in the U.S. District Court for Colorado. Meanwhile, FDA filed a similar complaint in the U.S. District Court for Nebraska and the Government seized 1,080 1½-pound cans of the same company's smoked quail being held by a consignee at Grand Island, Nebraska. At its plant, the company is voluntarily withholding distribution of 974 three-pound packages of frozen smoked pheasant and 765 1½-pound cans of smoked pheasant because of their content of the two additives.

"Partnership in Consumer Affairs" was the theme of the Rocky Mountain Consumer Officials Conference, held in Denver, to establish better communications and working relationships among city, county, State, and Federal officials functioning in various areas of consumer protection. Planning for the conference was led by Helen Keaveny, consumer affairs officer in FDA's Region VIII office in Denver, and head of the Denver Federal Executive Board. Officials from eight states attended to discuss various types of fraud, credit and housing problems, advertising and trade practices, and other subjects affecting consumers.

State Actions

Oyster Beds Closed

Several oyster beds along the lower Mississippi River were closed to harvesting until the high bacteriological levels caused by spring floods have been reduced. Dr. William H. Stewart, Director of Public Health for the State of Louisiana, took the action after water sampling showed higher than permissible levels. The east bank of the river in Plaquemines Parish, and the west bank near the town of Empire, were affected.

All Out of the Family

Star Bakery, a retail establishment in Detroit, is changing owners as a result of action by the Michigan Department of Agriculture. The bakery has a court his-

tory dating back to 1955. Since that time, the bakery has been prosecuted eight times because of insanitary conditions.

The judge trying the case imposed a jail sentence of 90 days on the owner, but gave the defendant the option of paying a fine of \$100 instead, should the business be sold to someone outside the family. The owner chose to sell. The trial followed State findings of insanitary conditions during an inspection in December 1974.

Carolinian Commissioned

FDA commissioning credentials have been presented to Dr. E. Kenneth Aycock, Commissioner of the South Carolina Department of Health and Environmental Control, Columbia, by Richard J. Dawson,

director of investigations, FDA Region IV, Atlanta. Dr. Aycock is the first individual in the department ever to be commissioned by FDA and is the only State official in South Carolina commissioned at present to carry out FDA activities.

New York Penalties

New York State Agriculture Commissioner Frank Walkley reported that during a recent month, the Department settled 281 cases for \$24,000 in civil compromise penalties. The Department took action against 407 firms and individuals for violation of the State's pure food and economic fraud laws, 126 cases being referred to the State Attorney General when the Department could not reach prompt settlement.

Seizures and Postal Service Cases

SEIZURE ACTIONS charging violation of the Federal Food, Drug, and Cosmetic Act are published when they are reported by the FDA District Office.

A total of 24 actions to remove from the consumer market products charged to be violative was reported in March. These included 22 seizures of foods: 3 involved charges concerning poisonous and deleterious substances, 18 involved charges concerning contamina-

tion, and 1 involved charges concerning economic and labeling violations. Other seizures included 2 of drugs (including 1 of veterinary medicated feed).

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD/Poisonous and Deleterious Substances		
Crowder peas/Atlanta, Ga. 3/5/75	Southland Frozen Foods/Plant City, Fla. (P,S)	Contain the added deleterious substance sandburs.
Milk solids, nonfat dry/City of Industry, Calif. 2/21/75	Plainview Milk Products Assn./Plainview, Minn. (M,S)	Contains penicillin, a new animal drug without approved New Animal Drug Application.
Potatoes/Los Angeles, Calif. 11/20/74	Morrow Produce Co./Boardman, Oreg. (S)	Contain chlordane, a pesticide chemical, for which no tolerance has been prescribed.
Contamination, Spoilage, Insanitary Handling		
Almonds/Boston, Mass. 12/26/74	Haig Berberian, Inc./Modesto, Calif. (P,S)	Prepared, packed, and held under insanitary conditions; insect contaminated.
Black-eyed peas, canned/Highlands, Tex. 3/7/75	SMS Div. of Hi-Port Industries/Highlands, Tex. (D,M)	Prepared under insanitary conditions.
Breading/Old Monroe, Mo. 12/20/74	Sun Ring Foods/Old Monroe, Mo. (D)	Held under insanitary conditions; rodent gnawed.
Brownie Mix/Tallahassee, Fla. 2/5/75	William E. Greene Food Distributors, Inc./Tallahassee, Fla. (D)	Held under insanitary conditions.
Candy banks/Memphis, Tenn. 1/15/75	Old Dominion Peanut Corp./Norfolk, Va. (M,S)	Unfit for food, contain metal fragments.
bars/Miami, Fla. 2/12/75	Ward Candy Co./New York, N.Y. (M,S)	Insect contaminated.
Cheese, Brie, Camembert/East Boston, Mass. 2/11/75	Imported from Saint Mihiel, France.	Decomposed.
Chocolate coating, chocolate rabbits/New Orleans, La. 2/18/75	Merlin's Candies, Inc./New Orleans, La. (D,M)	Held under insanitary conditions; rodent contaminated.
Crabmeat, Snow/St. Paul, Minn. 3/12/75	Shipped from Seoul, Korea.	Decomposed.
Flour/Toledo, Ohio 2/28/75	The Bartley Co./Toledo, Ohio (D)	Held under insanitary conditions; rodent contaminated.
Food, various/New Orleans, La. 2/25/75	P.A. Menard, Inc./New Orleans, La. (D)	Held under insanitary conditions; rodent and insect contaminated.
Macaroni rings and shells, spaghetti, egg noodles/Black River Falls, Wis. 1/16/75	BRF Wholesale Co./Black River Falls, Wis. (D)	Held under insanitary conditions.
Milk, nonfat, dry protein fortifier/East Greenwich, R.I. 12/26/74	East Greenwich Dairy Co./East Greenwich, R.I. (D)	Held under insanitary conditions; rodent gnawed.
Nuts, mixed/Independence, Mo. 2/21/75	A.L. Schutzman Co./Brookfield, Wis. (M,S)	Insect contaminated and rancid.
Soft drinks/Wichita, Kans. 3/11/75	Seven-Up Wichita Bottling Co./Wichita, Kans. (D)	Prepared and packed under insanitary conditions; contain mold.
Sugar, flour/Lohman, Mo. 2/28/75	Lohman Milling Corp./Lohman, Mo. (D)	Held under insanitary conditions; insect contaminated (flour).
Walnuts/Somerville, Mass. 12/24/74	Haig Berberian/Modesto, Calif. (M,S)	Prepared, packed, and held under insanitary conditions; insect contaminated.
Wheat/Bloomington, Calif. 1/20/75	Quick Seed & Feed Co./Phoenix, Ariz. (S)	Held under insanitary conditions; bird contaminated.
Economic and Labeling Violations		
Chewing gum/Winslow, Maine 12/26/74	Gum Products Inc./East Boston, Mass. (M,S)	No accurate statement of quantity of contents.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
DRUG/Human Use		
Vinivita tablets/Birmingham, Ala. 2/11/75	King Pharmaceutical Co./Birmingham, Ala. (D)	Below purported strength.
Veterinary/Medicated Feed		
Gervimone-V capsules/Elyria, Ohio 12/31/74	C.M. Bundy Co./Cincinnati, Ohio (M,S)	New animal drug without approved New Animal Drug Application.

U.S. POSTAL SERVICE actions taken in medical cases as authorized in the Mail Fraud Statute (18 U.S.C. 1341) and/or the False Representation Statute (39 U.S.C. 3005) as reported by the Chief Postal Inspector.

Complaints Filed by Law Department Under 39 U.S.C. 3005 (False Representation)

January 23, 1975: **Dr. Fairweather**, 138 Spring Valley Road, Oradell, New Jersey 07649 and Biosearch Industries Ltd., P.O. Box 943, Englewood Cliffs, New Jersey 07632. Advertising and sale by mail of a simple to read, practical book, that will enable readers to cure cancer in 2 months or less.

January 24, 1975: **Sonja of Sweden**, 520 Fifth Avenue at New York, New York 10036. Advertising and sale by mail of the newly discovered Swedish Bosom Developing Cream Formula, with superpenetrating living moisture concentrates, guaranteed to increase the size of the female bustline up to 5 or more inches.

January 29, 1975: **Arway Co.**, Box 173, Malone, Florida 32445 for advertising and sale through the mail of a product called "new love potion."

February 12, 1975: **C. West Distributors**, 3547 Columbine Dr., San Jose, California 95127. Advertising and sale by mail of Cacalia represented to be an effective medication for diabetes.

February 14, 1975: **Staminex**, Post Office Box 373, Southport, Connecticut. Advertising and sales by mail of a substance which allegedly increases stamina and mental alertness.

False Representation Orders Issued by Judicial Officer Under 39 U.S.C. 3005

January 23, 1975: Against **Vita E Diet**, 11526 Burbank Blvd., North Hollywood, California 91601. Advertising and sale by mail of a pill represented to be effective for weight loss.

February 13, 1975: Against **Ginseng + E Oil and/or Marco Polo Imports**, 11526 Burbank Blvd., North Hollywood, California 91601. Advertising and sale by mail of an oil represented to be effective for several skin maladies.

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Frog legs, frozen, at Decatur, S. Dist. Ill.

Charged 7-1-74: when shipped by E. J. Kozin Co., Inc., Brownsville, Tex., the article contained the added poisonous and deleterious substance viable *Salmonella* microorganisms; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 59854; S. No. 96-118 H; N.J. No. 1)

Potatoes, Desert Magic, 4 seizure actions, at Dallas, N. Dist. Tex.; Fort Worth, N. Dist. Tex.; Fort Worth, N. Dist. Tex.; and Jackson, S. Dist. Miss.

Charged on or about 11-27-74, 11-27-74, 12-3-74, 12-5-74: when shipped by Desert Magic, Inc., Boardman, Oreg., the articles contained the added pesticide chemical chlordane, in excess of the tolerance; 402(a)(2)(B). Default decrees ordered destruction. (F.D.C. Nos. 60103/4, 60107/8; S. Nos. 90-649 H, 90-274 H, 4-697 H, 59-541 H et al.; N.J. No. 2)

Swordfish loins, frozen, at Portland, Dist. Maine.

Charged 10-31-74: when shipped as whole fresh swordfish from waters outside the territorial limits of Maine, the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 60041; S. No. 109-702 H; N.J. No. 3)

FOOD/Contamination, Spoilage, Insanitary Handling

Catsup, at Oconomowoc, E. Dist. Wis.

Charged 11-18-74: when shipped by Naas Foods, Inc., Portland, Ind., the article, labeled in part "Land O'Lakes Tomato Catsup . . . Oconomowoc Canning Co., Distributors, Oconomowoc, Wis.," contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60074; S. No. 91-885 H; N.J. No. 4)

Cheese, wieners, pie mix, flour, and other grocery stocks in burlap, cloth, paper, Pliofilm, and similar packaging, at New Orleans, E. Dist. La.

Charged 10-18-74: while held by Schwegmann Bros. Giant Supermarkets, New Orleans, La., one lot of pie mix contained insect filth, various lots of cheese, wieners, and flour contained rodent filth, and the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 60037; S. No. 54-611 H; N.J. No. 5)

Cocoa powder, defatted, at Camden, Dist. N.J.

Charged on or about 6-26-74: while held by International Cocoa Products, Ltd., Camden, N.J., the article had been held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 59850; S. Nos. 56-991 H, 56-994 H; N.J. No. 6)

Coffee beans, at Brooklyn, E. Dist. N.Y.

Charged 11-8-74: while held for sale, the article contained insects and moldy coffee beans; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 59537; S. No. 72-074 G; N.J. No. 7)

Flour, Gilt Edge, at Richmond, S. Dist. Ind.

Charged 10-18-74: when shipped by Henry Nagel & Son, Cincinnati, Ohio, the article had been prepared and packed under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60018; S. No. 93-724 H; N.J. No. 8)

Flour and grits, at New Orleans, E. Dist. La.

Charged on or about 4-15-74: while held by George W. Groetsch Wholesale Grocer, New Orleans, La., the articles were held under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 59750; S. No. 53-965 H et al.; N.J. No. 9)

Flour, garbanzo beans, cornmeal, rice, and other food stocks in containers of burlap, cloth, paper, Pliofilm, and similar material, at New Orleans, E. Dist. La.

Charged 9-16-74: while held by George W. Groetsch Wholesale Grocer, New Orleans, La., some lots of flour and one lot of garbanzo beans contained rodent filth, and all the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 59975; S. No. 54-547 H; N.J. No. 10)

Ketchup, at Rocky Mount, E. Dist. N.C.

Charged 1-25-74: when shipped by Fettig Canning Corp., Elwood, Ind., the article, labeled in part "Grade A Fancy Red & White Brand Tomato Ketchup . . . Distributed by Red & White International Division of Federated Foods, Inc., Des Plaines, Ill.," contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59619; S. No. 6-147 G; N.J. No. 11)

Peanuts, shelled, at Cincinnati, S. Dist. Ohio.

Charged 11-5-74: while held for sale, the article contained the poisonous and deleterious substance aflatoxin; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 60058; S. No. 94-442 H; N.J. No. 12)

Pecans, shelled, Finer Foods, at Charleston, Dist. S.C.

Charged 5-14-74: when shipped by Finer Food Sales Co., Inc., Richmond, Va., the article contained insect filth; and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents statement was expressed as "Net Wt. 16 oz." instead of "Net Wt. 16 Ozs. (1 Lb.)"; 15 U.S.C. 1453(a)(3)(A)(i). Default decree ordered destruction. (F.D.C. No. 59760; S. No. 116-721 H; N.J. No. 13)

Rice, spaghetti, flour, spaghetti, vermicelli, gravy mix, lasagna, macaroni shells, and macaroni elbows, at Brooklyn, E. Dist. N.Y.

Charged 11-22-74: while held by Collus-Brooks Restaurant Supply, Brooklyn, N.Y., the articles contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.O.C. No. 60086; S. No. 43-169 H et al.; N.J. No. 14)

Scallops, frozen, at Brooklyn, E. Dist. N.Y.

Charged 7-15-74: while held for sale, the article contained decomposed scallops; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59863; S. No. 41-962 H; N.J. No. 15)

Soups of various kinds, 2 seizure actions, at Philadelphia, E. Dist. Pa., and Boston, Dist. Mass.

Charged 9-29-71 and 1-13-72: when shipped by Bon Vivant Soups, Inc., Newark, N.J., the articles, labeled in part "S.S. Pierce Red Label . . . Vichyssoise Cream Soup [or other kind of soup] . . . Packed for S.S. Pierce Company, Boston, Mass.," were unfit for food in that some cans of these foods had been found to be defective and abnormal, and in that the manufacturing procedures used did not assure proper sealing of the cans or adequate heat treatment of the sealed cans to prevent contamination and spoilage; and the articles had been prepared, packed, and held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decrees ordered destruction. (F.D.C. Nos. 57481, 57754; S. Nos. 23-871 E, 55-035/6 E; N.J. No. 16)

Tomatoes, canned, at Rochester, W. Dist. N.Y.

Charged 3-8-74: while held for sale, the article was contained in rusty, dented, and leaking cans; 402(a)(3). Consent decree authorized release to Ragú Foods, Inc., Rochester, N.Y., for salvaging. (F.D.C. No. 59689; S. No. 19-118 G; N.J. No. 17)

Warehouse food stocks in containers of burlap, cloth, paper, Pliofilm, and similar materials, at New York, S. Dist. N.Y.

Charged 1-3-75: while held by Transit Trading Corp., New York, N.Y., the articles were held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 60164; S. No. 44-014 H et al.; N.J. No. 18)

FOOD/Economic and Labeling Violations

Gum, bubble, Chu Mor, at Winslow, Dist. Maine.

Charged 12-20-74: when shipped by Gum Products, Inc. (subsidiary of Moxie Industries), East Boston, Mass., the article was approximately 6 percent short weight; 403(e)(2). Default decree authorized donation to a government institution. (F.D.C. No. 60142; S. No. 424 H; N.J. No. 19)

VITAMINS/SPECIAL DIETARY FOODS

Hi-Proteen vegetable powder, Hi-Proteen Gain Weight tablets, and Hi-Proteen Geriatric Formula powder, at Denver, Dist. Colo.

Charged 8-4-72: when shipped by York Barbell Co., Inc., York, Pa., the labeling of the article was false and misleading as follows: Hi-Proteen vegetable powder—the case label statement, "Hoffmann's Hi-Proteen Veg. Powder A Good Health, Energy and Body Building Food," falsely and misleadingly represented and suggested that the article would produce a strong, healthy, and energetic body; the package label contained statements which falsely and misleadingly represented and suggested that the article, when taken as directed, was a valuable nerve, muscle, and tissue builder; that it served as a catalyst in the utilization of incomplete proteins in the diet; that a small amount of the product would greatly improve the usual diet; that it was more completely digested and assimilated than other proteins; that it was especially result-producing in supplementing and sustaining food for workers, body builders, and athletes who have long periods of competition; that the article was essential for growth, particularly in children, in building new tissue after surgery and in wasting illness; that the article was of especial value for older people; that it was adequate and effective as a restorative to overcome physical and mental fatigue; that the article, when taken as directed, supplied the bodily needs for building, maintenance, and repair, and would keep the body well-nourished and the appetite satisfied; that class A anhydrous protein was a recognized superior grade of protein; that the article was an excellent source of energy-producing carbohydrates; that physicians regularly prescribed the article as a health, energy, and body-building food; and that any family would greatly benefit from the article; the photographic reproduction alleged to be Bob Hoffman appearing on the package label and the package label statements "Bob Hoffman World Famous Olympic Coach, the designer of HI-PROTEEN, and the author of the book 'Better Nutrition'"; "A profound knowledge of nutrition as well as proper exercise is required to build a body like this," "Bob weighs 266-1/2, has a 52 inch chest, is 6'3" in height, and lifted 282 pounds overhead with one arm," falsely and misleadingly represented and suggested that the article, when used as directed, was adequate and effective to build an extremely strong athletic body with tremendous muscles; Hi-Proteen Geriatric formula powder—the case label statement "Hoffman's Hi-Proteen Geriatric Formula A Good Health, Energy and Body Building Food," falsely and misleadingly represented and suggested that the article was of especial value for older people, and would produce strong, healthy, and energetic bodies for the aged; the name of the article and the statement on the front display panel of the package label, namely, "Hoffman's Geriatric Formula More proteins vitamins minerals," falsely and misleadingly represented and suggested that the nutritional requirements of older people are substantially different from other persons, and that older people re-

quired more protein, vitamins, and minerals than persons of all other age groups; the package label contained false and misleading statements which represented and suggested that old age was slow starvation which the article could prevent; that the article would result in a longer prime of life; that it would prolong life; that the article was adequate and effective in working and fighting against body changes to an amazing degree; that the article was adequate and effective in resisting infections, viruses, conjunctive cells and tissues, and other diseases which lead to premature old age and death; that it was never too late to reverse the aging process; that the article was a complete food containing a well-balanced blend of nutrients and good complete proteins of rare nutritional value, rarely if ever found in the usual diet; that a product containing no cholesterol was of particular value in the diet of the aged; that the article was of significant overall value in the diet of the aged but was low calorie; that class A anhydrous protein was a recognized superior grade of protein; and that the geriatric diet required the addition of amino acids; the label representation of 90 calories under the heading of "One Oz. of Geriatric Formula Contains" on the package label, and the listing of "Calories per oz. 80" under the heading "Geriatric Formula-Typical Analysis" on the package label were false and misleading, since they were contradictory; the listing on the package label of specific amino acids in the article was misleading, since the label failed to reveal the material fact that there was no need to supplement the diet with amino acids; the listing on the package label of amino acids in a 100-gram portion of the article was misleading, since 100 grams of the article was more than three times the portion of 1 ounce which was suggested on the package label to be taken daily, and such fact was not likely understood by the ordinary consumer; Hi-Protein Gain Weight Tablets—the case label statement "Hoffman's Hi-Protein Gain Wt. Tab. A Good Health, Energy, and Body Building Food," falsely and misleadingly represented and suggested that the article would produce a strong, healthy, and energetic body; the name of the article "Hoffman's Gain Weight Hi-Protein Famous Strength and Muscle Building Tablets" on the package label of the article falsely and misleadingly represented and suggested that the article was adequate and effective for gaining weight and building strength and muscles; the package label of the article contained statements which falsely and misleadingly represented and suggested that 90 percent of the people in our society did not get enough of the right kind of protein and that this was the chief reason they failed to gain weight; that the article was adequate and effective to complete or supplement any inadequate diet, to supply the elements the body must have for maintenance, repair, and building; that the article was adequate and effective to build strength and muscle and add body weight at a rapid pace, to increase weight and strength of athletes, and to provide fuel for the power, the speed, the muscle, and the added body weight an athlete must have to be a champion in his sport; that most diets were deficient in complete protein; that to gain weight every person required at least 100 grams of protein, and that larger, more active persons should have 300 grams of protein daily; that since the article was used by U.S. Olympic teams it was a better quality protein than was otherwise available; that growth and adding body weight required the addition of phenylalanine, leucine, valine, and tryptophan to the diet; that egg albumen was the protein most like human muscle; that there was now a new milk source; that class A anhydrous protein was a recognized superior grade of protein; that the article was superior to other proteins because it resembled human muscle in amino acid composition; that weight could not be gained unless the body has a protein surplus; that 40 tablets of the article per day (supplying 156 calories) would supply a sufficient amount of nutrition upon which to gain weight and build muscles and strength regardless of the individual's dietary needs; and that those 40 tablets would supply all the missing elements in the diet for such purposes—403(a); the labels of Hi-Protein vegetable powder and Hi-Protein Gain Weight tablets lacked the common or usual name of each ingredient, since ingredients stated on the package label such as "Mira-Soy, a natural soy powder, which is used only in Hoffman products," "a special milk source concentrate," "egg albumen," and "a special soy protein which is 90 % of complete protein" were not the common or usual names of ingredients—403(i)(2); and the labels of the Hi-Protein vegetable powder and Hi-Protein Geriatric Formula powder lacked required information concerning the articles' vitamin and mineral properties—403(j). Default decree ordered destruction. (F.D.C. No. 58168; S. Nos. 33-884 F, 33-887/8 F; N.J. No. 20)

FOOD ADDITIVES

Aloe vera gel and aloe vera juice, at Compton, C. Dist. Calif.

Charged 4-21-72: when shipped by Aloe Products, Inc., Houston and Hunt, Tex., the articles contained the nonconforming food additive aloe vera—402(a)(2)(C); and the articles were in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not separated from other printed label information appearing above (gel) and below (gel and juice) the declaration; since the quantity of contents statements, appearing on principal display areas of more than 5 square inches, were in a type size less than 1/8 inch high; and since quantity of contents statements of the juice and one lot of gel were expressed as follows: (juice) "16 fl. oz.," and (gel) "1 pint," instead of each being expressed as "16 fl. oz. (1 pint)"; and since the quantity of contents of the other lot of gel was not expressed in terms of fluid measure—15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i). Default decree ordered destruction. (F.D.C. No. 57945; S. Nos. 92-623 E, 92-633 E; N.J. No. 21)

DRUGS/Human Use

Duocept bismuth ammonium citrate and belladonna alkaloids combination solution, at Greensboro, M. Dist. N.C.

Charged 4-25-73: while held by Mayrand Inc., Greensboro, N.C., who manufactured the article using ingredients shipped in interstate commerce, the article's bottle label, insert, and accompanying instruction leaflet contained false and misleading claims that the article was generally recognized as a safe and effective treatment for peptic ulcer; and the article's labeling lacked adequate directions for use for its intended purpose, and was not exempted therefrom, since it was a new drug without an effective approved New Drug Application; 502(a), 502(f)(1). The article was claimed by the

manufacturer, who denied the charges and claimed that the article was entitled to the protection of the grandfather clause of the Drug Amendments Act of 1962. The Government served written interrogatories on the claimant. Subsequently, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 59156; S. No. 1-306 G; N.J. No. 22)

Epoxyite CPF tooth fissure sealant kits, at Columbus, S. Dist. Ohio.

Charged 2-22-72: when shipped by Lee Pharmaceuticals, South El Monte, Calif., the article was a new drug without an effective approved New Drug Application—505(a); and the kit vials of yellow, white, and red liquids lacked the name and place of the manufacturer, packer, or distributor, lacked an accurate statement of quantity of contents, lacked the established names of the liquids, and lacked the established name of each active ingredient of the liquids—502(b)(1), 502(b)(2), 502(e)(1)(A)(i), 502(c)(1)(A)(ii). Decree ordered destruction. (F.D.C. No. 57836; S. No. 25-688 F; N.J. No. 23)

Levamphetamine succinate capsules, at Miami Beach, S. Dist. Fla.

Charged 2-22-74: while held for sale, the labeling of the article lacked adequate directions for use, and the article was not exempted therefrom, since there was no effective approved New Drug Application; 502(f)(1). The article was claimed by Harry Needleman, M.D., Miami Beach, Fla., who denied the charge and moved to dismiss the action. The claimant asserted that he only dispensed the article as part of medication for his patients in the regular course of his medical practice, that the article was exempted from 21 U.S.C. 352(f)(1) due to 21 U.S.C. 353(b)(2) and 21 CFR 1.106(b)(1)(C). The claimant also moved for summary judgment, asserting also that, in the claimant's opinion as a physician, the article was not a new drug, that the article was not in transit and was in the possession of a licensed practitioner which possession exempted the article, and that physicians purchasing such drugs for their patients had no need of directions for use, since, of necessity, such physicians would have to know how to use such drugs before purchasing them. The claimant's motion to dismiss was denied, and the Government moved for summary judgment in favor of the Government. In denying the claimant's motion for summary judgment and in granting partial summary judgment to the Government, the court said:

"The Court has first considered whether the article of drug qualifies for the exemption from 21 United States Code, §352(F)(1) provided by 21 C.F.R. 1.106(g). Under 21 C.F.R. 1.106(g) a new drug shall be exempt: (1) to the extent such exemption is claimed in an approved application for the drug under 21 United States Code §355 or (2) if a notice of claimed investigational exemption under 21 United States Code 355(i) and 21 C.F.R. 312.9 (130.3) for the drug has been filed with the Food and Drug Administration.

"Claimant has not urged this exemption because in his opinion as a physician the seized article of drug is not a 'new drug.' Plaintiff asserts the seized drug is a 'new drug' within the meaning of 21 United States Code §321(p) but the exemption does not apply since neither a new drug application nor a notice of claimed investigational exemption pursuant to 21 United States Code, [§355(i) and 21 C.F.R. 321.1 (130.3)] applicable to Amordril Spancap, the seized drug, has been filed with the Food and Drug Administration.

"In support of its allegation that the seized Amordril Spancap is a 'new drug,' plaintiff submitted the affidavit of pharmacist Albert Lavend[e]r. Mr. Lavend[e]r informs the Court that he has reviewed the labeling of the seized drug and that the label states the contents of each bottle contain capsules of 'Levamphetamine Succinate.' He further states based on his knowledge and experience as a pharmacist that Amordril Spancap is a levamphetamine preparation within the scope of the August 8, 1970 announcement, 35 F.R. 12652, 12653 and 21 C.F.R. 310.504(c) and so is a 'new drug' for which an approved NDA is required. * * *

"Claimant in his answer and affidavit in support of his motion for summary judgment states that Amordril Spancap has been available by prescription for over five years and thus in his opinion as a physician is not a 'new drug.' The fact that a drug has been marketed for a period of years has no relevancy to a determination of whether it is a new drug within the statutory definition of 21 United States Code, §321(p). A 'new drug' is a drug which is not generally recognized by qualified experts as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereon. 21 United States Code §321(p). The Supreme Court has held that to satisfy the standard of general recognition of effectiveness and thus establish that a drug is not a 'new drug,' there must be 'substantial evidence' of effectiveness as that term is defined in 21 United States Code §355(d) and implementing FDA regulations at 21 C.F.R. 314.11(A)(5)(ii) [previously 21 C.F.R. 130.12(a)(5)(ii)] *Weinberger v. Hynson, Westcott and Dunning*, 412 U.S. 625, 629-632(1973). The substantial evidence standard requires well controlled clinical investigations by qualified experts to prove effectiveness of the drug. Consequently, this Court holds claimant's unsupported denial is insufficient to prevent a finding that the instant Amordril Spancap, a levamphetamine, is a 'new drug.' *Scarboro v. Universal C.I.T. Credit Corporation*, 364 F.2d 10, 15 (5 Cir. 1966). * * *

"Second, the Court must determine whether the instant article of drug qualifies for the prescription drug exemption of 21 C.F.R. 1.106(b) from 21 United States Code §352(f)(1). To acquire the 21 C.F.R. 1.106(b) exemption the labeling on or within the package from which the prescription drug is to be dispensed must bear adequate information for its use as defined in 21 C.F.R. 1.106(b)(3)(i) and if the article is a new drug, the label bearing such information is the label authorized by the approved new drug application. 21 C.F.R. 1.106(b)(3)(ii). The regulation does provide, however, as follows:

That the information required by subdivision (i) of this subparagraph may be omitted from the dispensing package if, but only if, the article is a drug for which directions, hazards, warnings and use information are commonly known to practitioners licensed by law to administer this drug. 21 C.F.R. 1.106(b)(3)(iii).

Plaintiff by the affidavit of pharmacist Lavend[e]r establishes there is no NDA in effect for Amordril Spancap. Therefore, the label requirement of 21 C.F.R. 1.106(b)(3) that the label be authorized by an approved NDA cannot be met. The instant article of drugs will

not qualify for the 21 C.F.R. 1.106(b) exemption unless the aforesaid quoted proviso applies and consequently satisfies the 21 C.F.R. 1.106(b)(3) requirement. Whether Amordril Spancap comes within the proviso is a question of fact for trial.

"As a third consideration in determining whether the instant drugs are misbranded within the meaning of 21 U.S.C. §352(f), the Court must decide if the prescription drug exemption of 21 U.S.C. §353(b)(2) applies as alleged in claimant's motion for summary judgment. The plaintiff argues the exemption is effective only at the time the prescription drug is dispensed, given into the hands of the patient, and not during possession of the drugs prior to that time. The legislative history of the Amendment which added 21 United States Code, §353(b) to the Act supports this interpretation. * * *

"This Court concludes that a prescription drug becomes exempt from the labeling requirements of 21 United States Code, §352(f) pursuant to 21 United States Code, §353(b)(2) only at the time the drug is dispensed to a patient. During the time prior to distribution the drug is subject to 21 United States Code, §352(f) requirements. A question of fact remains as to whether the instant article of drugs was in the possession of claimant and not yet dispensed to patients when it was seized.

"Claimant incorrectly contemplates that the 'held for sale' concept applies only to pharmacists and others engaged in the pure cash-for-product transactions and not to physicians who dispense drugs in relation with other medical services. The cases uniformly hold that use of a drug during a physician's treatment of his patients falls within the scope of the 'held for sale' requirement of the Act."

After trial by the court, the court found for the Government and ordered the article destroyed. The claimant's motion for rehearing was denied, as was a subsequent motion for a new trial. (F.D.C. No. 59820; S. No. 038-686 H; N.J. No. 24)

Roo-Hee herb medicine for gas & constipation, Hindu Magic liniment, Taj salicylic acid corn remover, and other finished, or in process, drugs and drug components, at Detroit, E. Dist. Mich.

Charged on or about 7-12-74: while held by Taj Perfume Co., Detroit, Mich., who was manufacturing and distributing drugs using components shipped in interstate commerce, the circumstances used for the articles' manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; and the part of such articles, which had been manufactured or were in the process of manufacture by the dealer, were articles which were manufactured in an unregistered drug establishment; 501(a)(2)(B), 502(a). Default decree ordered destruction. (F.D.C. No. 59869; S. No. 84-161 H et al.; N.J. No. 25)

Silicone liquid, at Hot Springs, W. Dist. Ark.

Charged 8-27-74: while held by Dowling Bluford Stough, III, M.D., Hot Springs, Ark., the article's labeling (including leaflet reading in part "Office Surgery... use of pure medical grade silicone," reprint entitled "Medical Silicone in Dermofacial Defects," and reprint entitled "Facts about Medical Silicone in Dermo-Facial Defects") lacked adequate directions for use, and the article was not exempted therefrom, since there was no effective approved New Drug Application and no Notice of Claimed Investigational Exemption was on file for the article; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 59907; S. No. 53-808 H; N.J. No. 26)

Stramonium and mephenesin combination capsules, at Denver, Dist. Colo.

Charged 10-4-74: when shipped by Stayner Corp., Berkeley, Calif., the article, labeled in part "S.A.M. ... Each Capsule Contains: Mephenesin ... Stramonium ... Manufactured for C & A Laboratories, Inc., Denver, Colo.," was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 59980; S. No. 80-655 H; N.J. No. 27)

DRUGS/Veterinary

Calif Preparation 10-4 sulfa and antibiotic combination livestock remedy, at Flanders, Dist. N.J.

Charged 4-2-73: when shipped by Provimi, Inc., Watertown, Wis., the article's label lacked the established name of each active ingredient, and the labeling lacked adequate directions for its intended purposes; 502(e)(1)(A)(ii), 502(f)(1). The article was claimed by the shipper. The Government served written interrogatories on the claimant. Subsequently, consent decree ordered destruction. (F.D.C. No. 59082; S. No. 64-244 G; N.J. No. 28)

MEDICAL DEVICES

Bedboard square, at Balko, W. Dist. Okla.

Charged 12-23-74: when shipped by Gary Boyer, Fritch, Tex., the labeling of the article, labeled in part "Jimmy Scribner Thermo Plant Board... MFG. BY: The World of Solarama Ltd.," contained false and misleading claims for reducing tension, inducing natural and healthy relaxation, benefitting the emotional tone and enhancing the psychological vigor of human beings, and relieving pain; and the labeling lacked adequate directions for use for its intended therapeutic purposes, since such directions could not be written because the article was worthless for such purposes; 502(a), 502(f)(1). Default decree ordered destruction. (F.D.C. No. 60130; S. No. 88-405 H; N.J. No. 29)

Diapulse electromagnetic energy generator, at Calumet City, N. Dist. Ill.

Charged 12-21-72: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the article's accompanying labeling, such as a treatment chart, and leaflets entitled "Diapulse Therapy As An Adjunct in the Treatment of Herpes Zoster" and "Peripheral Blood Flow Measurements During Application of Pulsed High Frequency Currents," contained false and misleading claims for normal bone and tissue healing, sinusitis, infections, rheumatoid arthritis, and blood flow to peripheral areas; and the labeling of the article lacked adequate directions for use for its intended purposes, and neither adequate directions for lay use nor adequate directions for use by licensed practitioners could be written; 502(a), 502(f)(1). Subsequently, pursuant to Rule 41(a)(1)(i), the action was dismissed without prejudice as to the device; however, the accompanying labeling was surrendered to the U.S. marshal and a default decree ordered its destruction. (F.D.C. No. 58619; S. No. 19-756 F; N.J. No. 30)

Diapulse electromagnetic energy generators, 4 seizure actions, at Anna, E. Dist. Ill.; Cowen,

S. Dist. W. Va.; Des Moines, S. Dist. Iowa; and Chattanooga, E. Dist. Tenn.

Charged 5-29-73, 7-3-73, 7-11-73, 6-6-74: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' accompanying treatment charts and leaflets contained false and misleading claims, such as for infections, fractures, bursitis, arthritis, low back pain, and blood flow to peripheral areas; and the articles lacked adequate directions for use for their intended purposes, and neither adequate directions for lay use nor adequate information for use by licensed practitioners for the articles' intended use could be written; 502(a), 502(f)(i). Except for the Chattanooga, Tenn., action which went by default, the articles were claimed by their possessors or owners. The Government served written interrogatories in the Cowen, W. Va., and Des Moines, Iowa, actions, and moved for summary judgment in those and in the Anna, Ill., action. After hearings in the Anna, Ill., and Chattanooga, Tenn., actions, on the motions for summary judgment, the courts granted the Government's motions and condemned the articles. In the Cowen, W. Va., action, the claimants withdrew from the action and a default decree condemned the article. The condemned articles were ordered destroyed, except for the device at Chattanooga, which was released to FDA for exhibit and/or display purposes. (F.D.C. Nos. 58968, 59317, 59362, 59796; S. Nos. 22-442 G, 10-472 G, 46-834 G, 50-515 H; N.J. No. 31)

Diapulse electromagnetic energy generators, 3 seizure actions, at El Dorado, W. Dist. Ark.; Columbus, S. Dist. Ohio; and Beaver, S. Dist. W. Va.

Charged 9-18-72, 10-27-72, 9-27-73: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' labeling lacked adequate directions for lay use for the articles' intended purposes, and adequate information for use by licensed practitioners could not be furnished; 502(f)(1). The articles were claimed by the possessors. The Government served written interrogatories on the claimants. In the Columbus, Ohio, action, a consent decree was entered ordering the article destroyed. In the other actions, the claimant failed to answer the interrogatories, and the Government moved for default decrees based upon claimant's failure to answer the interrogatories. Default decrees were granted in such actions ordering the articles destroyed. (F.D.C. Nos. 58261, 58419, 59473; S. Nos. 53-777 F, 25-782 F, 10-835 G; N.J. No. 32)

COSMETICS/BEAUTY PRODUCTS

Alvera shampoo, Alvera skin freshener & astringent, aloe vera after-shave lotion, and other aloe vera cosmetics, at Compton, C. Dist. Calif.

Charged 4-21-72: when shipped by Aloe Products, Inc., Houston and Hunt, Tex., the carton label of the aloe vera after-shave lotion lacked the place of business of the manufacturer, packer, or distributor—602(b)(1); and all the articles were in violation of the Fair Packaging and Labeling Act as follows: since all of the articles' quantity of contents declarations, appearing on principal display areas of more than 5 square inches, were in a type size less than 1/8 inch high; since the quantity of contents declarations of the Alvera shampoo and the aloe vera after-shave lotion were not separated from other printed label information appearing above the declaration; since the quantity of contents declarations of the aloe vera moisture creme and the aloe vera cleansing creme were not within the bottom 30 percent of the principal display panel area; and the quantity of contents statement of the aloe vera after-shave lotion was not expressed on the principal display panel in terms of liquid measure—15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Default decree ordered destruction. (F.D.C. No. 57945; S. No. 44-502 F et al.; N.J. No. 33)

Long Nails methyl methacrylate monomer fingernail lengthener kits, 7 seizure actions at Atchison, Dist. Kans.; Garland N. Dist. Tex.; San Jose, N. Dist. Tex.; Henderson, E. Dist. N.C.; Austintown, N. Dist. Ohio; Phoenix, Dist. Ariz.; and Phoenix, Dist. Ariz.

Charged on or about 9-9-74, 9-13-74, 9-5-74, 9-6-74, 9-25-74, 11-12-74, 11-12-74: when shipped by C.E.B. Products, Inc. (formerly Dark Eyes Co., Inc.), Chicago, Ill., the articles contained the poisonous and deleterious substance methyl methacrylate monomer, that might render the article injurious when used as directed or as ordinarily used; 601(a). Default decrees ordered destruction. (F.D.C. Nos. 59911, 59939, 59951/2, 59959, 60030/1; S. Nos. 75-515 H, 87-812 H, 26-768 H, 116-922 H; 95-919 H; 68-395 H; 68-268 H; N.J. No. 34)

NOTICES OF JUDGMENT on Criminal Actions

FOOD

Gerald C. Balsdon, t/a Jerry's Market, Evansville, S. Dist. Ind.

Charged 4-5-72: food warehouse stocks such as candy, flour, and rice were held in a building accessible to insects and rodents, and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (F.D.C. No. 57732; S. No. 38-845 D et al.; N.J. No. 35)

General Wholesale Cooperative Co., and Maynard P. Howard, secretary-treasurer, at Norfolk, Dist. Nebr.

Charged 9-20-74: peanuts (count 1), flour (count 2), gelatin mix (count 3), and pectin (count 4) were held in a building accessible to rodents and exposed to contamination by rodents, and the peanuts (count 1) were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation (all counts); fine, plus costs. Nolo contendere plea by individual (count 1); fine, plus costs. (F.D.C. No. 59847; S. No. 39-030 F et al.; N.J. No. 36)

Gressinger & Sons, William D. Gressinger, partner, Belle Glade, S. Dist. Fla.

Charged 9-23-74 by grand jury: 4 Brothers brand parsley bore and contained the added poisonous and deleterious pesticide chemical nitrofen (also known as TOK E-25 and 2, 4-dichlorophenyl p-nitrophenyl ether) in excess of the tolerance; 402(a)(2)(B). Guilty plea by partnership; fine. Nolo contendere plea by individual; fine and probation. (F.D.C. No. 59707; S. No. 13-721 G; N.J. No. 37)

Hawaii Grocers, Ltd., and Tomiji Yamamoto, executive secretary-manager, Hilo, Dist. Hawaii.

Charged 10-19-73: sweet rice was held in a building accessible to rodents, birds, and insects, and was contaminated with insects; 402(a)(3), 402(a)(4). The defendants pleaded not guilty, moved for a bill of particulars and discovery, and moved to dismiss

the action on the grounds that the statutory provisions were too vague and indefinite to charge an offense and as applied to the acts charged were unconstitutional, and that the information failed to indicate the penalty provision and, if 21 U.S.C. 333(a) was intended, the defendants would be immune from criminal prosecution by virtue of 21 U.S.C. 333(c)(1). The court denied the motion to dismiss, but allowed in part the motion for a bill of particulars and discovery. Subsequently, the defendants pleaded guilty and were fined. (F.D.C. No. 58187; S. No. 73-852 G; N.J. No. 38)

Kitchen Maid Bakery, and Arild D. Johnson, partner, Seattle, W. Dist. Wash.

Charged 1-25-74: when shipped, Kitchen Maid soya bread had been prepared under insanitary conditions; 402(a)(4). Guilty plea by partnership; fine suspended. Guilty plea by individual; fine. (F.D.C. No. 59406; S. No. 77-657 F; N.J. No. 39)

Tumbull Cones of P.R., Inc., and Alberto Bruno, president, Hato Rey, Dist. P.R.

Charged 4-5-74: ice cream cone mix was held in a building accessible to rodents and insects and was contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Nolo contendere plea by individual; fine and probation. (F.D.C. No. 59174; S. No. 65-276 G; N.J. No. 40)

NOTICES OF JUDGMENT on Criminal Actions

DRUGS

American Hospital Supply Corp., t/a Harleco Div. of American Hospital Supply Corp., Philadelphia, E. Dist. Pa.

Charged 4-5-74: when shipped, canned HarleCola carbonated glucose cola beverage (for glucose tolerance testing) had been processed, packed, and held under circumstances lacking current good manufacturing practice, since suitable specifications and test methods were not used, and the cans of the article were not sealed so as to prevent leakage, resulting in the cans containing less than the declared amount of glucose; 501(a)(2)(B). Guilty plea; fine. (F.D.C. No. 59239; S. Nos. 41-581 E, 47-967 E; N.J. No. 41)

NOTICES OF JUDGMENT on Injunction Actions

Alabama Renderers, Inc., and W. Howard Vickers, president & general manager, Montgomery, M. Dist. Ala.

Charged 3-29-73 in complaint for injunction: that the defendants were engaged at their plant at Montgomery, Ala., in processing and distributing in interstate commerce, foods for use in animal feed consisting of feather meal, and meat and bone meal, which foods contained the added poisonous and deleterious substance *Salmonella* micro-organisms, and which foods had been prepared, packed, and held under insanitary conditions; that FDA inspection had disclosed the existence of a number of specified insanitary conditions at the plant, and that despite a number of warnings, the defendants continued to manufacture and distribute such foods; 402(a)(1), 402(a)(4). The defendants consented to a decree of permanent injunction enjoining them from the violations complained of and from shipping in interstate commerce any animal by-products processed at the plant, unless and until a number of specified conditions were met, excepting that, for not more than 60 days, feather meal from the defendants' plant would be shipped with appropriate safeguards, directly to a North Carolina decontamination facility, for bringing into compliance with the law. (Inj. No. 640; S. No. 809 F et al.; N.J. No. 42)

Charles A. Andola, t/a Costa Apple Products, and Charles M. Andola, general manager, Highland, S. Dist. N.Y.

Charged 6-11-73 in complaint for injunction: that the defendants were engaged in preparing apple cider from apples which were in part rotten, and which had been received in intrastate and interstate commerce, and were engaged in selling and distributing apple cider in interstate and intrastate commerce; that the culling procedures for removal of apples having rotten spots was inadequate; that FDA analyses revealed mold in the in-line apples, and in the apple pomace resulting from the preparation of apple cider; and that despite warnings, the defendants continued to prepare and distribute apple cider consisting in part of a decomposed substance; 402(a)(3). A consent decree permanently enjoined the violations complained of, and enjoined the interstate shipment of apple cider and the preparation of apple cider from apples received in interstate commerce, unless and until a number of procedures were established to assure that the apple cider was not prepared from rotten apples. (Inj. No. 642; S. No. 91-848 F; N.J. No. 43)

C. H. Coward & Co., t/a F. H. & E. H. Miller and t/a Miller Bros., and H. Clifford Miller, partner, Byron, W. Dist. N.Y.

Charged 6-14-73 in complaint for injunction: that the defendants were engaged at their plants at Byron, N.Y., in receiving, processing, packing, and holding wheat and beans and in selling and distributing in interstate commerce such wheat and beans, which contained bird, rodent, and/or insect filth, and which were held under insanitary conditions, and that the defendants were well aware that their activities were in violation of the law; 402(a)(3), 402(a)(4). Consent decree enjoined the complained of violations, and enjoined the interstate shipment of any food held at the defendants' plant unless and until a number of specified sanitary practices were effected, including bringing into compliance the food on hand. (Inj. No. 646; S. No. 18-666 G et al.; N.J. No. 44)

Linden Laboratories, Inc. (Cromalloy American Corp. subsidiary) and Leo Linden, president and chairman of the board, Los Angeles, C. Dist. Calif.

Charged 6-12-73 in complaint for injunction: that the defendants were engaged at their plant at Los Angeles, Calif., in manufacturing, processing, packing, labeling, holding, and distributing in interstate commerce, various drugs, and in holding for sale, drugs, after shipment of one or more of their components in interstate commerce; that FDA inspections showed that there were a number of specified inadequacies in the defendants' operations; that a number of drugs had been recalled and a number had been seized by the Government; that FDA analyses revealed that a number of the defendants' drugs were in violation of the law; that the circumstances used for the manufacturing, processing, packing, and holding of such drugs failed to conform with current good manufacturing practice; that some of the drugs were new animal drugs, and no approvals of New Animal Drug Applications were in effect with respect to their use or intended use; that the strength, quality, and purity of some of the drugs differed from or fell below their own standard, or the U.S.P. or N.F. standards; that a substance had been

substituted in whole or in part for some drug component; that the labeling of some drugs contained false and misleading statements with respect to the identity, strength, quality, and purity of some drugs; that the labeling of some drugs lacked adequate directions for use, and lacked adequate warnings against unsafe use; and that the defendants were well aware that their activities were in violation of the law; 501(a)(2)(B), 501(a)(5), 501(b), 501(c), 501(d)(2), 502(a), 502(f)(1), 502(f)(2). A consent decree of permanent injunction enjoined the complained of violations, and enjoined the shipment in interstate commerce of any drugs prepared at the defendants' plant and enjoined the preparation of any drug while held for sale after shipment of one or more of its components in interstate commerce, unless and until a number of specified conditions concerning good manufacturing practice were met by the defendants, all the drugs on hand had been examined by FDA, appropriate recalls made, and the tested and recalled drugs were destroyed or otherwise brought into compliance with the law. (Inj. No. 648; S. No. 24-141 E et al.; N.J. No. 45)

Penn Tallow Co., and Charles D. Gross, vice president, Pittsburgh, W. Dist. Pa.

Charged 5-17-73 in complaint for injunction: that the defendants were engaged at their plant at Herrs Island, Pittsburgh, Pa., in processing and distributing in interstate commerce, dry rendered tankage for use in animal feeds, which tankage contained the added poisonous and deleterious substance *Salmonella* micro-organisms, and which tankage had been prepared, packed, and held under insanitary conditions; that FDA inspections revealed a number of specified insanitary conditions; that FDA analyses showed *Salmonella* micro-organisms present in the defendants' in-process and finished food, and that, despite warnings, the defendants continued to manufacture and distribute such tankage; 402(a)(1), 402(a)(4). Consent decree of permanent injunction enjoined the complained of violations and enjoined the shipment of dry rendered tankage for use in animal feed from defendants' plant, unless and until a number of specified sanitary practices were effected, except that such tankage could be shipped under appropriate safeguards directly to a North Carolina decontamination facility for treatment. (Inj. No. 645; S. No. 67-709 F et al.; N.J. No. 46)

NOTICES OF JUDGMENT on Miscellaneous Actions

Alertonic pipradrol hydrochloride, vitamins & minerals combination elixir, and proposed withdrawal of its NDA, declaratory judgment suits, Dist. Del.

Charged 8-27-70 in complaint for declaratory judgment by Richardson-Merrell, Inc., a Delaware corporation, against H.E.W. Secretary Elliot L. Richardson and FDA Commissioner Charles C. Edwards: that plaintiff had filed a New Drug Application for the elixir in 1956, which application had become effective the next year; that FDA had advised the plaintiff in 1958 that the article was no longer regarded as a "new drug"; that following the Drug Amendments of 1962 which added the criteria of efficacy to the definition of "new drug," the FDA had published a notice of intention to withdraw approval of the New Drug Application as part of the implementation of Drug Efficacy Study reports received from the National Academy of Sciences—National Research Council; that the plaintiff had submitted evidence of efficacy of the elixir; that FDA, after discussing with the plaintiff and reviewing such evidence, had written the plaintiff that FDA intended to initiate proceedings to withdraw plaintiff's New Drug Application for Alertonic elixir; that further proceedings by FDA would irreparably injure the elixir's reputation and that the court was requested to declare Alertonic to be not a "new drug" and to enjoin the defendants from proceeding any further to withdraw Alertonic's New Drug Application and from attempting to enforce against the plaintiff or Alertonic in any other action the requirements of the Federal Food, Drug, and Cosmetic Act relating to "new drugs."

The plaintiff having given approved security, the court issued a temporary restraining order against the defendants enjoining them for 15 days, from instituting any further proceedings to withdraw Alertonic elixir from the market. The plaintiff also moved for a preliminary injunction. After a hearing, the court permitted the temporary injunction to expire and took the plaintiff's motion for a preliminary injunction under advisement. Subsequently, the plaintiff moved to dismiss the action on the grounds that the Government had stated at the hearing that the Government would provide the plaintiff with an opportunity to have the "new drug" questions determined in the course of administrative proceedings. Accordingly, the action was ordered dismissed. (Misc. No. 150; N.J. No. 47)

Contaminated poultry, action to require testimony of FDA employees, N. Dist. Ala.

Petitioned 1-8-71 by Buster Haynes, poultry flock owner, against FDA Division Director Taylor M. Quinn, FDA Inspector John Yount, and the Department of Health, Education, and Welfare, for an order to show cause why defendants should not be required to offer testimony in a civil suit for damages in the Cullman County Circuit Court of the State of Alabama, which petition was based on the following: that the civil suit for damages of **Buster Haynes vs. Cook's Pest Control** sought damages for the negligent administration of chemicals in and around Haynes' poultry house thereby causing pesticide contamination to his eggs and laying flock; that John Yount had discovered the contamination; that Haynes had been informed that his eggs and hens could not be sold in interstate commerce and that his flock had to be destroyed; that on the defendants' advice and instructions, Haynes' flock was destroyed and several cases of eggs destroyed; that Haynes had requested that Yount's testimony be made available in the civil suit for damages; that Taylor M. Quinn had written that Yount's testimony would not be available; that such refusal to allow Yount to testify was arbitrary and unreasonable; and that such testimony and disclosure by the defendants would not be incompatible with the public interest, but in fact would be of general benefit to the public. The Government moved to dismiss the petition on a number of grounds, including lack of proper service on the individual defendants, failure to state a claim upon which relief could be granted, and lack of Federal jurisdiction. The Government asserted that Taylor M. Quinn replied to and fully answered the Haynes' requests; that Yount had obtained the Government's information from Haynes and Cook Pest Control Company and had no direct knowledge of the cause of the pesticide contamination; that Federal courts could not be used solely to secure evidence for use in a State court proceeding; that the Government, while opposing testimony at trial of Yount, would make Yount available for deposition on those facts concerning which he had personal knowledge; and that none of the jurisdictional requirements had been alleged, and it

was clear that no jurisdictional base could be established. Thereafter, the court granted the Government's motion and dismissed Haynes' petition. (F.D.C. No. 167; N.J. No. 48)

Milnot blend of fat-free milk and soya oil, canned, declaratory judgment suit, S. Dist. Ill. Charged 10-1-70 and amended 6-21-71 in a complaint for declaratory judgment by Milnot Co., Litchfield, Ill., against H.E.W. Secretary Elliot L. Richardson: that the plaintiff processed and marketed the food product "Milnot" which consisted of a vitamin A & D fortified blend of fat-free milk and vegetable soya oil, which blend and its components were nutritive substances and of such quality that they complied with all applicable Federal standards; that the product was marketed in intrastate commerce; that Milnot was not bought, sold, or ordered in imitation or in semblance of evaporated, condensed, or concentrated milk, but was bought, sold, and ordered under its distinctive proprietary name; that Milnot was sold in hermetically sealed cans; that the defendant permitted in interstate commerce the sale of imitation milk, imitation milk products, and products that contained filled milk; that Milnot was a milk substitute; that the defendant took the position that Milnot was subject to the provisions of the Filled Milk Act; that, though the defendant permitted in interstate commerce similar products, the defendant threatened the plaintiff with prosecution in the event that it similarly marketed Milnot in interstate commerce; that such exclusion of Milnot from interstate and foreign commerce violated due process, was a result of an unjustified distinction between Milnot and competing products, and was a denial of the right to equal protection of the law; and that plaintiff prayed that the court declare that Milnot was not subject to the Filled Milk Act, and declare that plaintiff had the right to market Milnot in interstate and foreign commerce free from any prosecution for violation of the Filled Milk Act.

The Government contended that the article was filled milk within the definition of the Federal Filled Milk Act; that the Milnot was undistinguishable from evaporated whole cow's milk, except by careful chemical analysis, which revealed the presence of soybean oil in place of butterfat; that the legislative history of the Filled Milk Act specifically named the plaintiff's "Carolene" (a blend of evaporated skimmed milk and coconut oil) as one of the products prompting passage of the legislation; and that the Supreme Court had twice before decided that the Federal Filled Milk Act was constitutional and that the products Milnot, Milnot, and/or Carolene, of the plaintiff (using its former name of Carolene Products Co.), were within the statute's definition of filled milk when applied to such a product. The Government moved for summary judgment of dismissal as did the plaintiff. The court ruled in favor of the plaintiff saying in part:

COURT'S DISCRETION IN DECLARATORY JUDGMENT ACTION

"Defendant suggests, as an alternative basis for dismissal, that since this case involves a constitutional challenge, the court should exercise its discretion and decline to render a declaratory judgment. In development of this argument, defendant asserts that plaintiff's proper recourse is legislative rather than judicial. Assuming that the factual basis for the Filled Milk Act now does require review, the court is not at liberty to shut its eyes to a possible constitutional infirmity out of deference to Congress, when the validity of the law depends upon the truth of what is declared. *Chastleton Corp. v. Sinclair*, 264 U.S. 543 (1924). While this court most certainly does not sit as a 'super legislature,' weighing the wisdom, need, or general appropriateness of legislative policy, it must consider the possible violation of due process of law in existing declared policy. That remains for discussion here.

DUE PROCESS

"The measuring stick to which legislative acts must conform in order to satisfy due process has been stated in the previous *Carolene* decisions, *supra*. That is, regulatory legislation affecting ordinary commercial transactions is not to be pronounced unconstitutional unless, in light of the known facts, it is of such a character as to preclude the assumption that it rests upon some rational basis within the knowledge and experience of the legislators. *U.S. v. Carolene Products*, 304 U.S. 144, 152 (1938). And as previously stated, the constitutionality of a statute predicated upon the existence of a particular state of facts may be challenged by showing to the court that those facts have ceased to exist. *Chastleton Corp. v. Sinclair*, 264 U.S. 543 (1924).

"From the undisputed facts in the record here, it appears crystal clear that certain imitation milk and dairy products are so similar to Milnot in composition, appearance, and use that different treatment as to interstate shipment caused by application of the Filled Milk Act to Milnot violates the due process of law to which Milnot Company is constitutionally entitled. No useful purpose is served by listing such products here by name or otherwise, or by discussing the dairy market conditions and dangers of confusion which led to the passage and judicial upholding of the Filled Milk Act many years ago. Suffice it to say that this court finds that the latter have long since ceased to exist.

"It is true that equal protection of the laws does not require identical treatment among those similarly situated, but it does require that arbitrary or capricious distinctions not be made. *Wickard v. Filburn*, 317 U.S. 111, 129 (1942). It is uncontested that many of these imitation milk and dairy products contain as basic and primary ingredients skim milk and vegetable oil. The defendant does argue that certain of these products on the retail market are not 'in imitation or semblance of milk' to the extent that Milnot is. While each product, including Milnot, has, by design of its producer, its own unique taste, it appears clear that at least six other food products now moving in interstate commerce have almost identical appearance and consistency to milk (or evaporated milk) and to each other, both in the package and when poured. The defendant may well be correct in determining that each such product, other than Milnot, is not within the purview of the Filled Milk Act; but this circumstance seems simply to lend support to the conclusion that an act which produces such incongruous results regarding interstate shipment alone is devoid of rationality. The possibility of confusion, or passing off, in the marketplace, which justified the statute in 1944, can no longer be used rationally as a constitutional prop to prevent interstate shipment of Milnot. There is at least as much danger in this regard with imitation milk as with filled

milk, and actually no longer any such real danger with either.

"Similarly, the facts that Milnot legitimately appears on grocery shelves in the various states where it is produced, that there is a growing trend of manufacture and sale of filled milk overseas, and that there is widespread use thereof by American armed forces overseas, all add to the irrationality of the subject Act as applied to Milnot in this country. Prevention of confusion in the market, however valid in 1944, is no longer a valid basis to sustain the Filled Milk Act, and thus to prevent only the interstate shipment of Milnot (or any other product of milk which is **exactly** like it).

LABELING

"The Filled Milk Act applies to the contents and is not involved with labeling of the product. As the Supreme Court specifically recognized in the second *Carolene* case, the question of proper labeling is irrelevant to the issue of the constitutionality of the Act. 323 U.S. at 31. The evil of confusion in the marketplace clearly is one which Congress has the power to minimize by regulation, and this court does not here decide that Milnot is or is not properly labeled under various statutory provisions. Defendant refused to admit, on the request of plaintiff in this case, that Milnot is properly labeled; and that is a matter for resolution between the parties or further enforcement action by defendant; but it is a dispute of fact which is wholly immaterial to the decision here. This court limits its decision to the conclusion, as a matter of law, that the Filled Milk Act, as applied to prohibit interstate shipment of Milnot, deprives the plaintiff of due process of law and provides no rational means for the achievement of any announced objective of the Act.

"IT IS ORDERED, accordingly, that declaratory judgment enter herein, declaring that plaintiff has the right to market its product Milnot in interstate and foreign commerce, free from any prosecution or other interference from defendant for violation of the Filled Milk Act (Title 21, United States Code, Sections 61 thru 64)." (Misc. No. 152; N.J. No. 49)

Talodex fenthion injectable for dogs, judicial review of withdrawal of New Animal Drug Application, in the U.S. Court of Appeals for the 8th Circuit.

Petitioned 3-31-71 by Diamond Laboratories, Inc., Des Moines, Iowa (8th Circuit), against H.E.W. Secretary Elliot L. Richardson, and FDA Commissioner Charles C. Edwards, for review of the H.E.W. Secretary's order withdrawing the approval of the New Animal Drug Application for the petitioner's Talodex injectable. In upholding the order of the H.E.W. Secretary, the court said:

"In its Order withdrawing approval of New Animal Drug Application and denying Diamond's request for a hearing, the FDA accorded careful consideration to the argument advanced and the information furnished by Diamond in support of its request for a hearing. The Commissioner's evaluation of the facts before him at the time the Order was filed is delineated at 36 F. Reg., 3211-3212. This obviates the necessity of reciting here the Commissioner's analysis of the facts before him and his rationale in reaching his decision We have considered the Order in its entirety in light of the information and evidence submitted by Diamond and are satisfied that the FDA's action was fully warranted.

"Because of Diamond's strenuous contention on appeal that the FDA acted arbitrarily in denying it an opportunity to offer additional evidence at another hearing, we give this issue additional consideration.

"The statute, 21 U.S.C. §360b(e), . . . permits withdrawal of previously granted approval where:

new evidence not contained in [the original] application . . . shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved.

"As noted, the regulation, 21 C.F.R. 130.14(b), . . . authorizes denial of an evidentiary hearing prior to withdrawal of approval where the facts upon which withdrawal is to be based are not substantially at issue. Our analysis of the pertinent data forming the premise for the FDA's Order constrains us to hold that the Commissioner was justified in acting summarily without an evidentiary hearing. [Footnote] This holding is clearly justified by two grounds relied upon in the FDA Order withdrawing approval: (1) new evidence, including Diamond's own admission, that Talodex did indeed have a harmful additive effect, and (2) disparity between the mortality rate indicated in Diamond's original submission and that computed on the basis of reports from veterinarians and others using Talodex after its approval. See 36 F.Reg. at 3211-3212. Either ground alone would have been sufficient to authorize withdrawal of approval, particularly since Diamond did not controvert the facts basic to either ground. Consequently, no evidentiary hearing was required." (Misc. No. 166; N.J. No. 50)

Correction: In the February 1975 issue of FDA CONSUMER, on page 37, Notice of Judgment No. 24 erroneously implied that the article (enteric-coated urinary antiseptic tablets) was charged as being violative at the time of shipment and misleadingly associated the shipper with the charged violation. The article had actually been manufactured, successfully tested, and shipped some 6 years before it was charged as being violative; and the article was in fact charged as being violative "while held for sale after shipment in interstate commerce."

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

Notices of Judgment are prepared by Food and Drug Division, Office of the General Counsel, DHEW.

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

Alexander M. Schmidt, M.D., *Commissioner of Food and Drugs*
Washington D.C., May 1, 1975

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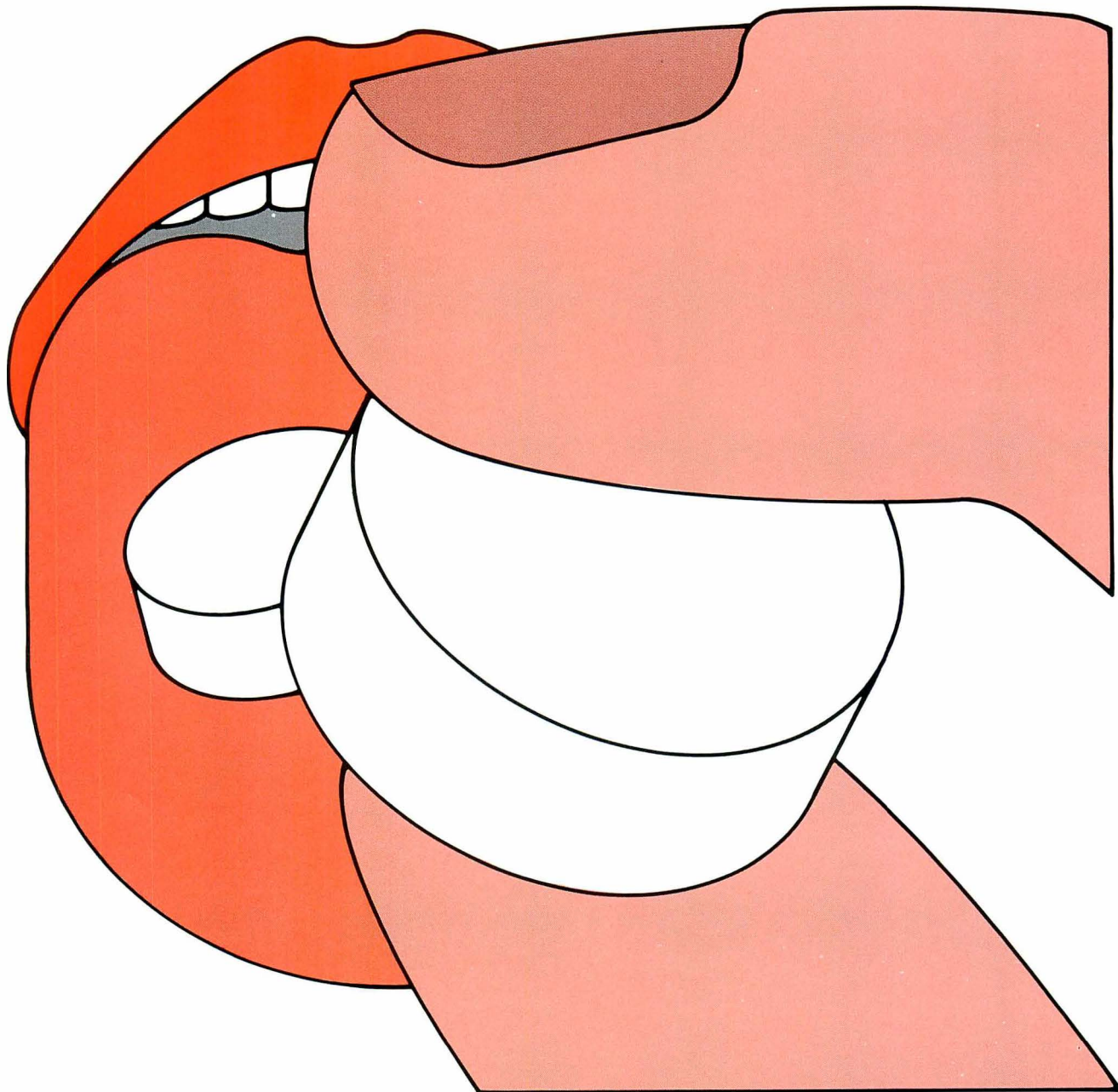
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But aspirin, like the thousands of other drugs you can

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