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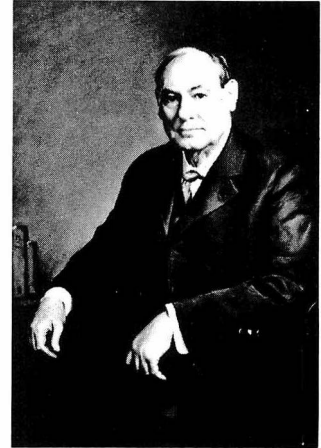
FDA PAPERS

AN OVERVIEW OF COSMETIC REGULATION

The Hexachlorophene Story

SPOTTING TROUBLE WHEN IT COUNTS





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

Harvey W. Wiley, 1844-1930

Father of the Federal Food and Drugs Act of 1906

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

The "agonizing decision," that unenviable process associated with statecraft and some other pursuits, is no stranger to FDA. Decisions are particularly agonizing in the regulatory field when they involve a product that has been widely used and accepted for some time. That was the case with hexachlorophene.

But wide use does not make a product immune to FDA action and ironically this wide use may lead to scientific observations and findings that weren't made, and perhaps couldn't have been made, the first time around. When this happens, a reappraisal may be in order.

"The Hexachlorophene Story" (see page 11) tells how a case was reopened and how FDA had to make a tough decision, based on new scientific evidence and benefits versus risks, in the interests of the consumer. That decision contemplates restricted but continuing use of this antibacterial in a way that utilizes the benefits and minimizes the risks.

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

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

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

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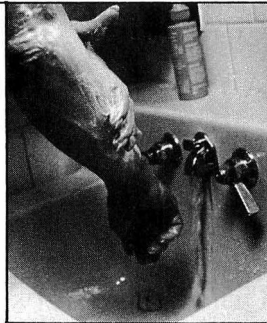
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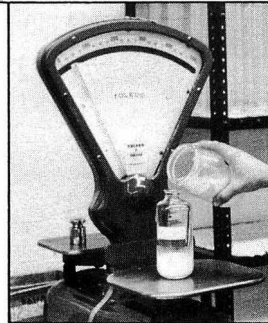
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AN OVERVIEW OF COSMETIC REGULATION



by Robert Schaffner, Ph.D.

Almost since Adam and Eve, men and women have used cosmetics to make themselves more attractive. The American supply is regulated by the Food and Drug Administration whose jurisdiction over the safety of cosmetics stems from the 1938 Federal Food, Drug, and Cosmetic Act. Robert Schaffner, director of the Office of Product Technology in FDA's Bureau of Foods, is a key contributor to the Agency's policies in the cosmetics area. In this interview with the editors of FDA PAPERS, Dr. Schaffner covers a wide variety of subjects, including:

- Consumer complaints.
- A new program with industry.
- Hexachlorophene.
- Feminine deodorant sprays.
- Aerosols.
- Color additives.
- Eye cosmetics.
- Hypo-allergenic cosmetics.

Q. *Dr. Schaffner, the National Product Safety Commission two years ago estimated that there are 60,000 cosmetic injuries a year in the United States. The cosmetics industry believes this is a gross exaggeration. How many cosmetic complaints does FDA receive each year?*

A. We have been keeping a tabulation of this for the last two years, although we are not sure the figures represent every complaint that has been received by FDA. In calendar year 1970, we received 227 complaints. For calendar year 1971, we received 314. Now, the increase from 200-odd to 300-odd does not necessarily mean that the toxicity of cosmetics has increased by 50 percent. The reason for the increase is due to the growing consumerism movement.

Speeches that the Commissioner and others have made and various publications have alerted the public that the Food and Drug Administration does supervise and regulate the cosmetic industry. Consequently, more people are writing to us than they did in the past.

Q. *What types of consumer complaints about cosmetics does FDA receive? Could you categorize them and give me some examples?*

A. All the complaints we receive involve adverse reactions or injury of some type. Complaints about labeling of the product, or about a broken jar, would not come to FDA but rather would go to the manufacturers.

We have broken down the cosmetic complaints into different classes of cosmetics. There have been some interesting changes in the past three years on some statistics. For example, for dentifrices and mouthwashes, in 1971 the complaints dropped to less than 4 percent, whereas in 1970 they were 9 percent of the total.

Q. *What types of complaints do you receive about dentifrices?*

A. Recent complaints, particularly in 1970, had to do with the possible inflammation of the gums. As a result of investigations we found that some manufacturers were using chloroform in their products, and chloroform had an adverse reaction on mucous membrane tissues.

This was brought to the attention of the manufacturers and they reformulated their products. We think that this reduction in percentage at least partially can be attributed to this reformulation.

Q. *Can you list other categories of cosmetic complaints?*

A. One class of complaints that increased from 1970 to 1971 was deodorants and antiperspirants. Complaints rose from 7 per-

cent in 1970 to almost 12 percent in 1971. There is, of course, a rather wide diversification of complaints about these products, but the increase in these complaints in 1971 can be largely attributed to feminine hygiene deodorant. Complaints on this subclass of products almost doubled in 1971.

The usual complaints about feminine deodorant sprays have to do with burning, rashes, and other inflammations. Our records indicate that when the product is discontinued, the problem usually goes away. We know this because we get in touch with the complainant in most cases.

The largest classification of complaints is on hair preparations. The reason may be that they represent the largest volume of cosmetic products. In 1970 hair preparations represented about 30 percent of all of our complaints, and rose in 1971 to almost 39 percent.

There has been a slight increase in complaints about hair dyes and color rinses, but last year we saw a significant increase in complaints about shampoos. They increased from 8½ to 14 percent. This can be attributed to some of the newer shampoos. As the result of discussions we have had with some of the manufacturers, investigations have been started and FDA is sponsoring some outside toxicology studies on one particular type of hair shampoo. We have some indications that the manufacturer may reformulate this product as a result of preliminary testing.

Another category that has been the subject of consumer complaints is bath preparations. In this connection, we are glad to see that bath preparation complaints have decreased as the result of FDA action. We found that some of the wetting agents, the sulfonates, were being used in too high a percentage in some bubble bath preparations. This was causing infections in some girls. The manufacturers, at our insistence, reformulated the products and these complaints have decreased, from 11 percent in 1970 to about 8 percent in 1971. Because of the reformulations made during 1971, we expect to see a further decrease in 1972.

Q. *Is there any way of telling what percentage of actual cosmetic injuries are reported to FDA?*

A. No, I don't think there is any good way of determining this. For all consumer products, neither the Government nor the industrial companies really know how many dissatisfied consumers are writing in. There have been various estimates made over the years that one out of ten unhappy people write in. Others have projected it is closer to one in a thousand. I don't think anyone really knows.

Based on figures and discussions we have had, however, we believe that the 200 or 300 complaints that we receive in FDA is a very small sample of complaints that are being registered with the manufacturers. Collecting injury complaints or adverse

COSMETIC INJURY COMPLAINTS

Cosmetic Class	1941-1970		1970			1971		
	Number	Percent	Number	Company	Percent	Number	Company	Percent
Baby Preparations	8	0.4	1	1	0.4	-	-	-
Bath Preparations	51	2.3	25	9	11.1	27	16	8.6
Creams-General	212	9.5	15	13	6.6	9	6	2.8
Dentifrices and Mouth Washes	47	2.1	21	6	9.4	12	7	3.8
Deodorants and Antiperspirants	136	6.1	16	10	7.0	37	17	11.8
Depilatories	49	2.2	3	3	1.3	2	2	.6
Detergent Bars	16	.7	4	4	1.8	4	3	1.3
Eye Preparations	128	5.8	16	16	7.0	22	13	7.0
Facial Makeup, Powder, and Rouge	70	3.2	8	8	3.5	15	15	4.8
Facial Packs, Masks, Straps, etc.	37	1.7	3	3	1.3	-	-	-
<i>Hair Cosmetics:</i>	(859)	(38.7)	(67)		(29.5)	(122)	(61)	(38.9)
Bleaches	-	-	3	3	1.3	6	4	1.9
Preparations	131	5.9	13	12	5.7	9	7	2.9
Dyes and Color Rinses	181	8.2	8	8	3.5	31	15	9.9
Shampoos	184	8.2	19	10	8.5	44	16	14.0
Straighteners	55	2.5	5	4	2.2	6	4	1.9
Wave Sets, Lacquers	125	5.6	12	10	5.3	18	11	5.7
Waves-Cold/Permanent	183	8.3	7	5	3.1	4	4	1.3
Hand Preparations	10	.5	1	1	.4	4	4	1.3
Leg Makeup	6	.3	-	-	-	-	-	-
Lipsticks	159	7.2	5	5	2.2	6	6	1.9
Lotions	55	2.5	-	-	-	4	3	1.3
Miscellaneous	88	4.0	6	6	2.6	12	10	3.8
Nail Preparations	149	6.7	14	11	6.2	11	10	3.6
Perfumes and Colognes	28	1.3	2	2	.9	7	6	2.2
Shave Preparations	22	1.0	3	3	1.3	4	4	1.3
Skin Bleaches and Lighteners	-	-	6	3	2.6	9	4	2.8
Skin Fresheners	-	-	6	3	2.6	4	3	1.3
Sunscreens and Suntan Preparations	82	3.7	5	4	2.2	7	5	2.2
Tattoo Pigments	3	.1	-	-	-	-	-	-
Totals	2,215	100.0	227		100.0	314		100.0

reactions on consumer experience on a much larger basis obviously would be much more meaningful for us. Because of limited manpower within the Agency, we have to work on the problems that affect the greatest number of consumers. We don't know at this time whether we are doing this, because of our very small sample.

Q. *Is there any way at the present time of categorizing the safety of the American cosmetic supply? Is the American consumer reasonably sure of receiving a safe cosmetic when he or she buys one in the pharmacy or supermarket?*

A. From what we know of the cosmetic industry, I believe the general safety record of cosmetics is quite good. Most of the larger manufacturers have extensive testing facilities. Some of the smaller ones that do not have their own facilities take a responsible position and have consulting laboratories test various cosmetic preparations.

We, of course, believe that all cosmetic products, regardless of how small or large their potential volume might be, must be adequately tested by the manufacturer before they are introduced to the general public.

Q. *By law, FDA doesn't have direct access to manufacturers' tests. Would you like to see the establishment of a system whereby manufacturers would voluntarily submit tests to FDA for evaluation, either before or after marketing, or when a great number of consumer complaints come in?*

A. Fundamentally, this would be a good thing to do. At the moment, however, we in FDA don't have the manpower and resources to handle testing data for every type of cosmetic product. Another problem is that manufacturers always like to have a jump on their competitors and consequently might hesitate to show others their test data. At the moment manufacturers come for-

ward with data as a group only when we or they are getting a large number of consumer complaints.

An example of this was the feminine deodorant sprays. It took a considerable amount of urging from FDA to get manufacturers to act in concert to give us at least some figures on the numbers of complaints per million units sold and the types of adverse effects that they were getting.

Q. *The most important recent regulatory development in the cosmetics area has been the publication by FDA of regulations proposed by the industry trade association, the Cosmetic, Toiletry and Fragrance Association (CTFA), which provide for voluntary registration with FDA of all manufacturing plants and the voluntary submission by manufacturers of the ingredients in their products, except for flavors and fragrances. What has FDA done to prepare for the mass of information that is expected to flow in?*

A. We have had a task force working on this since about the middle of 1971. The Bureau of Foods has never before had such a massive registration to cope with and therefore we brought in not only our scientists and our compliance officials, but also people who are involved in computer programs.

The registration of cosmetic manufacturing establishments is underway. This information will be put into a computer system so it can be rapidly retrieved. This took quite a lot of planning. The listing of ingredient information for cosmetics poses a more difficult problem because of the thousands of ingredients that are used in cosmetics and the different types of formulations.

I certainly hope that by July 1973 the system will be working smoothly. We are initially encouraged by the early indications we have been seeing on the registration of cosmetic establishments.

Q. *Dr. Schaffner, there are about a thousand cosmetic companies in the United States. About 25 percent are members of the CTFA—even though CTFA companies produce about 90 percent of the cosmetics. Do you have any idea at the present time how many companies are going to comply with this voluntary system proposed by CTFA?*

A. No, I think it's too early to determine how many are going to comply. Of course, one crucial question is whether those firms that agree to register as an establishment are also going to give us their formulations. Within a year or a year and a half we will know whether the program is a failure. An indication of this would be a low percentage of responses to the voluntary program. But it will take several years to be sure it is a success and is giving better protection to the consumer.

Q. *What does FDA intend to do with the information that is going to be on computer tape?*

A. We are going to have the computer tabulate different types of cosmetics and different types of ingredients, and then determine those ingredients which are "generally recognized as safe" and those on which not much toxicology data is available. We will then handle the ingredients as groups and not involve ourselves with each cosmetic product, because this task would be a never ending one. We wouldn't get the greatest consumer protection for the taxpayers if we tried to do them on this one-by-one basis.

Q. *The leaders of the cosmetic industry have indicated a willingness to open up their consumer complaint files to FDA as a third voluntary program. You said at one time that this third regulation is essential if the first two—namely the voluntary registration of cosmetic manufacturers and the listing of ingredients—are to work. Do you still believe this?*

A. Yes, I think this is fundamental. Really, the information from the first two programs might be called the "input" into the system. The "output" is the consumer complaints or adverse reactions or consumer experience or product experience, whatever term you wish to use.

If we have consumer complaints from several manufacturers on a particular class of products, we can determine from the formulation data whether they have common ingredients. We then will be able to put these things together and have some meaningful data on which to base regulatory action.

Q. *Commissioner Edwards has praised the Cosmetic, Toiletry and Fragrance Association for volunteering these programs. You indicated before, however, in regard to feminine hygiene deodorant sprays that the cooperation from industry was not as great as might be expected. In general, are you pleased with the cooperation you receive from the trade associations and from individual manufacturers?*

A. Generally we are pleased with the responsible attitude that the Association and its members are taking. Of course, there is always a certain adversary relationship between industry or an individual company and any regulatory body.

We try to minimize this and we try to have frank discussions, particularly on a scientific basis, between the scientists in the Food and Drug Administration and scientists in the industry. By working together we can find out where there are gaps in knowledge.

When it gets down to the cold facts of the matter, there are times when neither industry, Government, nor the academic world may have information that directly relates to the safety of some of the ingredients that are being used.

Q. *If that is the case, why is FDA allowing the continued marketing of some ingredients which have not been proven conclusively to be safe?*

A. The law clearly delineates the differences between the powers and responsibilities that FDA has with respect to various products. The manufacturers of drugs and foods must prove the safety of their products to FDA, but as far as cosmetics are concerned, FDA must prove the lack of safety or the toxic or deleterious effect of a cosmetic product before we can act on it.

Of course, it is difficult to prove safety in the first place, and when we start from the base of having to prove the lack of safety of a product, this puts a great deal of responsibility on our shoulders. It's an entirely different type of ball game.

Q. *In your view, can individual cosmetic manufacturers take additional voluntary action to provide greater protection for the American public?*

A. Through the education programs the CTFA is conducting, it can do a lot to educate manufacturers to follow good manufacturing practices and to perform premarketing research. However, there is no mechanism by which any association can force its members to carry out these practices.

CTFA, of course, is anxious to see that voluntary compliance programs are working, but it has no power. As in any industry, the reputation of the industry is sometimes at the mercy of the most irresponsible companies.

Q. *Well then, Dr. Schaffner, do you think that additional legislation is needed to provide the American consumer with greater protection from dangerous cosmetics? What is FDA's position on the need for cosmetics legislation?*

A. Our general position on the need for legislation really cannot be spelled out at this time. Basically, we believe that the voluntary program now underway will give the industry an opportunity. If it works, then there is probably no need for further legislation. If it doesn't work, then it seems to me that the industry will have had its opportunity and muffed it. And if they do muff it, I believe that the Administration will go to Capitol Hill and ask for legislation, perhaps putting the cosmetic industry on a status similar to the food industry.

It probably will take at least several years to de-

termine whether the voluntary program is going to succeed. I do think the voluntary program at this time is the best approach to take because, based on past legislative histories of other changes to the FDC Act, we've seen that it has taken many years to change or amend the law and in the interim the consumer is not being further protected.

By having this voluntary program in force now, we will be getting a greater measure of consumer protection, now. Another factor that must be taken into consideration is that our experiences with the voluntary program will enable the Administration to design the bills and regulations for a mandatory program that could be much more meaningful after we've had the experience with this voluntary program. I do not mean to imply that the voluntary program is necessarily the first step toward a mandatory program. We have to wait to see how the entire program works out to determine whether it is necessary to have further legislation.

Q. *Let's turn now to problems that have been brought up on specific products and ingredients. Everyone, of course, has been talking about hexachlorophene. FDA would like to limit its use to preservative status in cosmetics. Would this limitation result in the proliferation of bacteria in cosmetics, and are there other preservatives to which the industry can turn?*

A. The use of hexachlorophene in cosmetic preparations as a preservative usually involves its use as one of a group of chemicals in a preservative system. Other chemicals would have equal value as part of the system. However, if manufacturers are going to change from hexachlorophene to some other preservative, they must make sure that the new preservative system is not only effective but is relatively safe and nontoxic.

We believe that there is an implied warranty on the part of each cosmetic manufacturer to test his product before it is marketed. If a preservative has not been tested for safety, the public should be warned by the label.

We are concerned about bacterial contamination of cosmetic products. In fact, most recalls of cosmetic products during the past several years have been due to the bacterial contamination.

We are particularly concerned about the *Pseudomonas*-type organism being present in cosmetics that are used in the area of the eye or the face. These must be absent from cosmetic products that are used in this manner because serious eye injury can result if the products are contaminated with this family of organism.

Q. *Feminine hygiene deodorant sprays have been the subject of considerable discussion in the past few months. Some people have urged that they be banned and others have suggested that manufacturers be asked to prove a favorable benefit-to-risk ratio. What is FDA's current position on feminine hygiene deodorant sprays?*

A. The final settlement of this matter will rest undoubtedly in the reformulation and relabeling of some of these products. We feel that the term "hygiene" is not appropriate for these products because the word has medical inferences that have no place in a cosmetic.

We also believe most of the manufacturers are not labeling the products adequately. We are studying and working on a series of required statements that would be placed on these products. This is really in a sense a part of our undertakings on aerosol products. So, I think we'll see some changes in genital sprays.

However, I don't think FDA should decide whether these products should be sold or not. As long as they are sold as cosmetic products, and not as drugs, it seems to me we cannot take a position that certain types of cosmetic products are not appropriate.

Q. *You mentioned aerosols, the subject of considerable discussion. One physician in Colorado even tried to link the use of aerosols to lung cancer. Is there any evidence that aerosols pose a hazard to the American public?*

A. Late last year FDA set up a committee to study aerosols. It had representatives from all the Bureaus in FDA, as well as agencies such as the Environmental Protection Agency, which regulates aerosol products that contain pesticides.

We feel there have not been sufficient warnings on some aerosol products, and we think that this should be a matter of regulation, and not one of urging manufacturers to make changes. Sometimes, when we merely urge manufacturers to make changes, the so-called "good guys" have more explicit warning or caution statements, but often suffer in the marketplace at the expense of those who do not take a responsible position.

Therefore, we will have uniform aerosol labeling on different products for different uses. This will be across the whole line of household products—foods, cosmetics, drugs, cleaning preparations, furniture polishes, and the like.

Q. *Can you tell us, Dr. Schaffner, what the problems are with aerosols?*

A. Probably the most dramatic problem is that every once in a while, some teenager sniffs the contents of an aerosol container and dies as a result. Considerable publicity is given to many of these incidents. There is probably no way we can completely prevent them.

However, when a product can be abused, resulting in death or very serious health impairment, this should be told to the consumer. People who might, for kicks, want to abuse the product should at least understand the potential dangers.

Second, some instructions on aerosol cans are not

as explicit as they should be. Where there is a possibility of someone setting himself on fire from an aerosol product, the label should clearly warn about the need for sufficient ventilation. The labels of certain hair preparations should warn the consumer not to smoke for a period after using them. We intend to require any label warnings needed to inform consumers about the proper use of aerosols.

Q. *Is there any evidence that aerosol products such as underarm deodorants sprayed directly on the body over a continuous period of time pose an unusual hazard for the American consumer?*

A. No, I don't believe there is any evidence to clearly delineate that there is a hazard. I think, however, a little more explicit directions for usage on the aerosol might improve the use of those products, as well as others.

Q. *Let's turn to another subject for a moment. Colors are a vital ingredient in many cosmetics. Color additives that are used in foods are now being reevaluated and restudied by other elements in the Bureau of Foods. Is a similar program being undertaken for colors used in cosmetics?*

A. The program on colors really is more inclusive than just foods; it covers all of the colors used in drugs and cosmetics that may be ingested. This includes colors used in lipsticks and other cosmetics like mouthwashes and dentifrices. We are awaiting teratology and reproduction studies.

We are in the process of approving on a permanent basis other colors. This approval will extend only to use in products that are intended for external use. The approvals will be coming along in quite a stream this year.

We are getting one more piece of scientific information with respect to each of the colors. We want to make sure the colors are stable when they are carried through the manufacturing process. We have asked the cosmetic industry to prepare authentic samples for which the full history is known. Cosmetic preparations containing that color will be subjected to the most severe temperature and chemical conditions that they are normally subjected to in the manufacturing process.

If it is then proven that virtually all the color can be accounted for after this severe test, then we will permanently list the color for external uses.

Q. *Eye cosmetics pose an unusual hazard for consumers in two respects. First, eye cosmetics seem to be a good medium for the growth of bacteria. Second, eye cosmetics are applied to an unusually sensitive part of the body. What is FDA doing to assure the safety of eye cosmetics? Is there anything in particular that women can do to avoid hazards?*

A. We have supporting outside research and are doing some work in our Toxicology Division on eye cosmetics and other cosmetic products that get into the eye, such as sham-poops. We are also engaged in discussions with the scientific liaison committee of the CTFA to determine what it is doing on eye preparations.

We have a genuine concern for this class of cosmetic products. As far as American consumers are concerned, they should be careful in using these products to see that they do not abuse them. Of course, one of the most common abuses of an eye cosmetic is contamination introduced in the home after the product has been opened. For example, some women wet the eye preparation by spitting on it, and this can result in serious contamination.

The manufacturers try to take this into consideration when they add antibacterial agents to their eye preparations. But of course it would not be desirable for them to overload these products with antibacterial agents, because the level of the preservative could get so high that it could produce other toxic reactions.

Q. *This is a classic problem facing FDA—the question of benefit versus risk. That is, the benefit of putting a large amount of antibacterial agents in an eye cosmetic to reduce contamination versus the risk of having a quantity so large that it could be toxic. In evaluating the safety of drugs, the benefit-risk ratio can be somewhat easier to determine. How does one determine the benefit-risk ratio of cosmetics, or, in a broader term, how does one determine whether a cosmetic is safe?*

A. The benefit-to-risk ratio must be taken into consideration on any product. Certainly the ratios that might be applicable to drugs cannot be directly applied by any means to cosmetics, and we might wish to avoid the use of any ingredient, if it, for example, had a very desirable effect in some drugs but was unnecessary in a cosmetic product.

This whole matter of risk and safety is one for which no hard and fast guidelines can be devised. We have to make judgments by classes of products as questions occur.

Q. *Hypo-allergenic cosmetics are widely advertised and are presented as posing less risk than regular cosmetics for people who have allergies. Is there really such a thing as a hypo-allergenic cosmetic, and are some of these claims justified?*

A. I am sure that there are some products that might be accurately classified as hypo-allergenic. However, the term is a very loose one and we hope there may be some way for FDA and the manufacturers to more closely define some sort of a standard for the use of this term.

Q. *Should the American consumer spend extra money on a cosmetic that is labeled hypo-allergenic? Is it really worth extra money?*

A. I think each consumer would have to determine this for herself. Because the term is widely used and covers such a variety of products, we would not want to take a position that would endorse a product that was listed as a hypo-allergenic cosmetic.

Allergies are such a broad field that something that may be allergenic to one person would not have adverse effects on others. Each consumer has to determine this for herself.

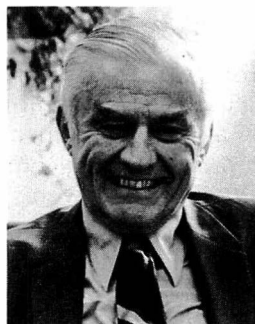
Q. *In general terms, what can the American consumer do to protect himself or herself from dangerous cosmetics?*

A. Well, the consumer must be sure that the product is being used according to the instructions. For hair dyes, for example, it is important that patch tests be performed before a product is used. On an overall basis, the more information we in FDA can get from the consumer, the better our regulatory program can be. We can provide greater safety to the consumer from products that are on the market.

Q. *What are FDA's priorities in the regulation of cosmetics?*

A. Our immediate plans are to involve ourselves deeply in the administration of the voluntary cosmetic programs that have been started. In addition, we have numerous research projects underway, and these will be continued. Investigations of groups of cosmetic products will be largely determined by the information that we receive from consumer complaints and as a result of the voluntary manufacturer program.

We believe that the incorporation of this program into our Bureau will bring about much more meaningful information, permitting us to create an overall program of better consumer protection. We think this will enable us to work on the most important subjects first and to give proper priority to them.



Dr. Schaffner

THE HEXACHLOROPHENE STORY

By Wayne L. Pines

The Food and Drug Administration's regulatory action to restrict the use of hexachlorophene was based mainly on three studies, reported in the past several months and concurred in by scientific experts, challenging the safety of the widely-used antibacterial drug.

The studies led to an FDA reappraisal of hexachlorophene to determine whether the benefits of its use in a large number of products and in hospital nurseries outweighed the risks to the public and especially to newborn infants. FDA concluded that hexachlorophene, when used incorrectly or indiscriminately, poses a potential hazard to both adults and children, and therefore should be restricted.

FDA's conclusion, and the regulatory actions stemming from it, have generated some concern and confusion among consumers and health professionals who have been using hexachlorophene on an unrestricted basis for up to 20 years with no apparent ill effects.

Story Starts in 1941

The hexachlorophene story, particularly its recent developments, cannot be told in black-and-white terms. It is a story that is still developing. The difficulty facing FDA is how to communicate this story to the American public, which is accustomed to outright bans on dangerous chemicals, but is not used to evaluating products, as FDA must, in terms of benefits and risks, and trying to strike a balanced regulatory position in the interests of all consumers.

The hexachlorophene story began in 1941, when W. S. Gump patented it. A Swiss-based company, Givaudan Corporation, developed it. Hexachlorophene's use grew and grew over the years. It has been an ingredient in creams, ointments, powders, cosmetics, toothpastes, antiperspirants, mouthwashes, feminine deodorant sprays. It has been used widely to treat burns and for daily cosmetic uses such as showering and skin care. Hexachlorophene has even been used in furnace filters and in plastics for shower curtains.

Hexachlorophene has been popular for a number of reasons. Everyone assumed its medical action was well-known and well-understood. It is a relatively insoluble chemical, which may have led to the belief that it could not be very potent. And FDA itself for some years did not

regard products containing hexachlorophene to pose a hazard to the public.

By today's standards, however, little was really known about hexachlorophene and its effects in humans until recently. One of the advantages was that repeated use caused hexachlorophene to build up on skin surfaces—which now presents a problem, because rinsing does not remove all the chemical.

Over the years, a number of cases of human poisoning were reported, but since they involved the ingestion of hexachlorophene, a purpose for which it was not used in the United States, they generated minimum concern. There were isolated cases of adverse reactions to hexachlorophene when used topically—that is, on the skin. One case, for example, involved a newborn infant who was treated by its mother with a 3 percent hexachlorophene detergent that was not rinsed off. After four days, the infant's face and buttocks peeled, and there was slight twitching of the arms, legs, and face that later led to convulsions. Hexachlorophene bathing was stopped, and 16 days later the infant was in good health except for still peeling skin.

A study in 1968 indicated that hexachlorophene was found in the blood of burn patients when applied topically. The investigator observed that hexachlorophene could actually pass through the burn wound and the skin into the bloodstream. When the level of hexachlorophene became sufficiently high in the blood, some patients went into convulsions. There were also other signs of nervous system problems: weakened legs, nausea, vomiting, and muscle irritability.

The Three Studies

Random observations and limited studies of hexachlorophene were all that was available until August 1971, when the first of three studies leading to the recent regulatory restrictions was published. This study was performed by Dr. Renate Kimbrough and Thomas Gaines, two scientists then working in FDA who were considering an application by a manufacturer who wanted to use hexachlorophene as an herbicide. Kimbrough and Gaines fed hexachlorophene to rats as part of their diet. After two weeks, the rats developed leg weakness which progressed in three to five weeks to paralysis. After hexachlorophene was discontinued, the rats regained use of their legs—indicating

that whatever damage is caused by hexachlorophene may be reversible.

Kimbrough and Gaines also found, however, that the brains of the hexachlorophene-fed rats were heavier than those of the rats in the control group. Lesions (abnormal spaces) were observed in the brains of the hexachlorophene-fed rats. The scientists concluded that indiscriminate and unnecessary use of hexachlorophene should be discouraged.

Dr. Kimbrough, now with the Environmental Protection Agency, took a broader look at hexachlorophene in another article published in August 1971. She undertook a thorough review of the scientific literature to collate what already was known about the chemical. She pointed out that hexachlorophene is absorbed through normal skin and that large doses of the chemical affect the central nervous systems of both humans and rats. Again, she urged that unnecessary use of hexachlorophene be discouraged.

The second study leading to the FDA regulatory restrictions related hexachlorophene to human babies. This study was reported by a team of scientists, including August Curley, Robert Hawk, and Dr. Kimbrough. It involved 50 newborn infants in a New York hospital who were washed once daily with a diluted hexachlorophene solution according to established hospital practice. None of the infants showed any toxic effects—but the investigators found the babies had absorbed hexachlorophene into their bloodstreams through normal, unbroken skin, and that the levels were close to the toxic levels in animals and man.

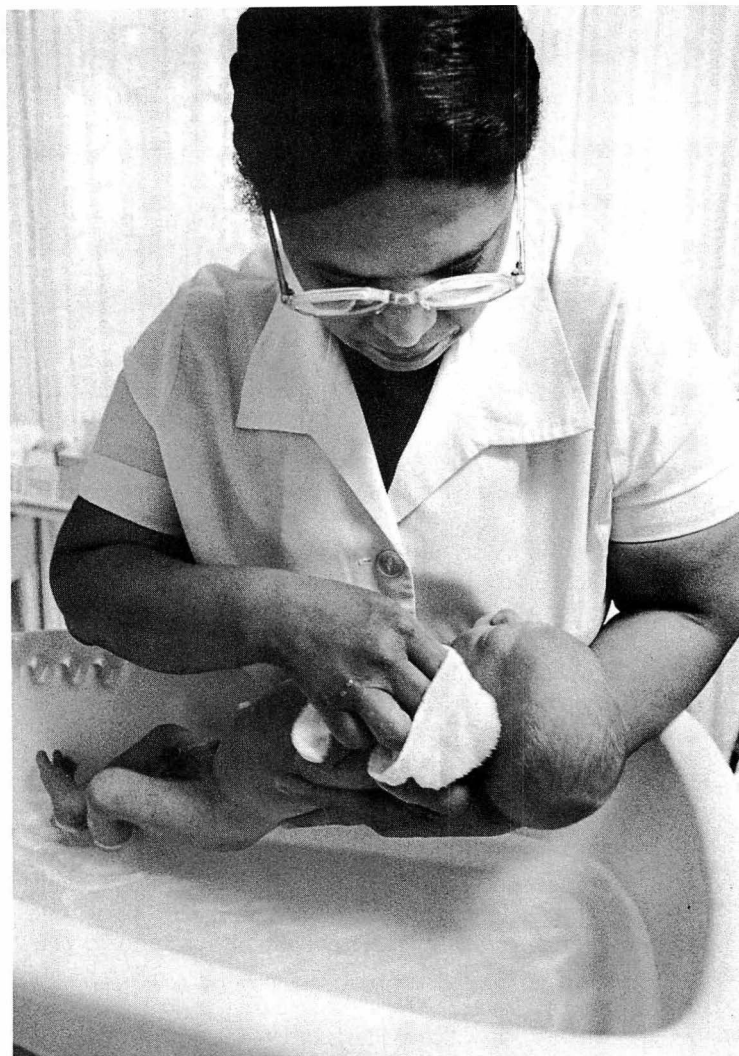
The third study was received by FDA in November 1971 from Sterling Drug, Inc., the manufacturer of the most widely used 3 percent hexachlorophene solution, pHisoHex. The study involved five newborn monkeys washed daily for five minutes with pHisoHex for three months in a manner simulating the washing of newborn infants. The monkeys showed no overt signs of adverse reactions—but autopsies revealed that the monkeys' brains had lesions similar to those observed in the brains of the rats that had been fed hexachlorophene. Monkeys washed similarly without hexachlorophene were normal.

Benefits and Risks

These three studies led to serious FDA concern about the widespread practice in hospital nurseries of bathing newborn infants routinely in 3 percent hexachlorophene solutions. In deciding what action, if any, was dictated by the studies, FDA applied a traditional scientific principle—the “benefit versus risk” concept. This means that FDA figuratively puts all the evidence on a scale, weighing the benefits of a product against its risks.

In the case of hexachlorophene and newborns, the benefit of bathing infants in 3 percent solutions was the reduction of the spread of some infections. Many hospitals used hexachlorophene in their nurseries for this purpose—although other modern hospitals had never used hexachlorophene for total body bathing of infants, and still had managed to keep infections to a minimum.

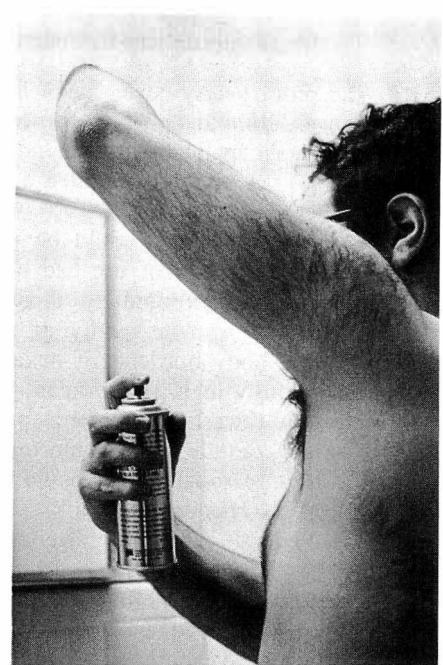
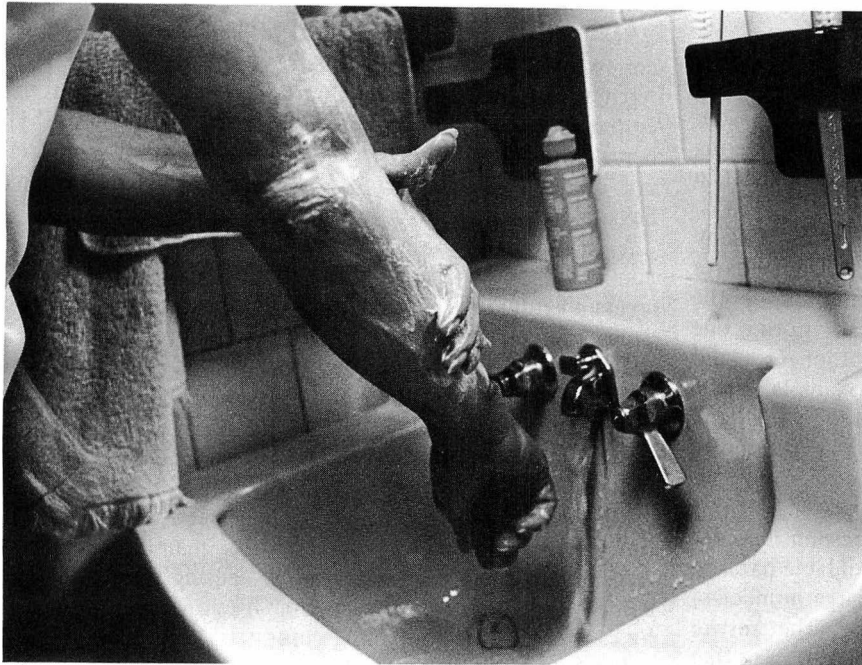
The risk of bathing infants in hexachlorophene solutions



could not be as well defined as the benefit. There was evidence that babies could absorb hexachlorophene through unbroken skin into the bloodstream. There was evidence that in monkeys, concentrates of hexachlorophene in the blood which caused no apparent change in behavior caused microscopic changes in the brain. The evidence also indicated that the average concentration of hexachlorophene in the blood of both rats and monkeys that were shown to have brain lesions was only twice the highest levels found in babies washed routinely in nurseries.

Thus, FDA scientists were faced with this question: Was the risk of brain damage in infants worth the benefit of helping to prevent skin infections in hospitals—infections that could be controlled by other means? FDA determined that the proper course of action, the only prudent course, was to recommend that total body bathing of infants be discontinued.

FDA met with representatives of the American Academy of Pediatrics (AAP) to discuss the studies. In early December, the Agency mailed to 600,000 physicians, osteopaths, and other health professionals a Drug Bulletin urging that babies no longer be bathed in 3 percent hexachlorophene solutions. The three studies, FDA pointed



out, “challenge the safety of hexachlorophene bathing of infants.”

The Committee on Fetus and Newborn of the American Academy of Pediatrics followed the FDA announcement with a similar recommendation. The Committee’s conclusion and recommendations were summarized in a “newsletter supplement” dated January 1:

“The safety of hexachlorophene bathing of infants with hexachlorophene-containing solutions has not been established. Blood levels found in newborn infants bathed daily in hexachlorophene solutions have been shown to approach levels known to be neurotoxic in experimental animals. Therefore, the use of hexachlorophene for total body bathing of newborn infants in hospital nurseries or at home is contraindicated.”

Recognizing that many hospitals had relied on hexachlorophene for several years in controlling infections in nurseries, the Committee suggested the following alternative:

“At present the Committee recommends dry skin care; washing with plain, nonmedicated soap and tap water; or washing with tap water alone for skin care of the newborn infant. It should be emphasized that the two most important factors in the transmission of infections from infant to infant are hand contact and breaks in technique. These factors can be minimized by scrupulous hand washing before entering the nursery as well as just before and just after handling each infant. Either iodophor preparations or 3 percent hexachlorophene emulsion are recommended for hand washing.”

Within a matter of weeks after FDA and the Committee issued their recommendations, some hospitals began reporting that staphylococcal infections had broken out in nurseries following discontinuance of hexachlorophene bathing. The reports flowed into the Center for Disease Control, an agency of the Department of Health,

Education, and Welfare that had asked hospitals to keep it up to date on infectious outbreaks. Some of the reports were brought to FDA’s and CDC’s attention by manufacturers that objected to the recommendations.

CDC considered the reports serious enough to request a meeting with FDA and AAP. It was held February 2, 1972, in FDA’s Washington headquarters. The data from the hospitals was found to be preliminary and difficult to evaluate because hospitals had never before reported these types of infections. The conclusions reached at the meeting were:

- Most of the reported outbreaks involved mild skin infections.
- Many hospitals had discontinued bathing infants without any infectious outbreaks.
- In some hospitals, nurses and other personnel had stopped washing their hands in hexachlorophene solutions before handling babies. This was contrary to the FDA and AAP recommendations.
- If an outbreak of nursery staph infections occurred, there should be a thorough reevaluation of hospital facilities and techniques to determine their adequacy.
- If hospital practices and facilities were found inadequate, and if infections did break out, *short-term* once daily bathing of infants in hexachlorophene should be considered, provided that the infants were rinsed thoroughly.

The sum of conclusions was that good hospital practices alone could control infections in nurseries, and that use of 3 percent hexachlorophene solutions is justified only when hospital practices fail. FDA and AAP remained opposed to routine total body bathing of infants with hexachlorophene. This is their position today. FDA and CDC are continuing to receive data from hospitals on outbreaks of infections in nurseries, and are maintaining their surveillance.

Hexachlorophene in General Use

While the controversy over hexachlorophene use in newborns was bubbling, FDA turned to the broader question of hexachlorophene for general use. In considering this problem, FDA scientists applied a second concept in addition to benefit versus risk:

Even if hexachlorophene could be used safely in any single product, its mode of use had become such that a consumer could be exposed to large amounts of the antibacterial agent from a variety of sources during one day. The "total body burden" of hexachlorophene could become dangerously high. If a woman, for example, used a toothpaste, mouthwash, deodorant, powder, cream and feminine spray containing hexachlorophene—a possibility that was not unreasonable—she could develop dangerous blood levels of the chemical.

Could a Federal regulatory agency, responsible for protecting the American consumer from avoidable hazards, permit the continued marketing of such a large number of products that contained hexachlorophene? The answer reached by Agency scientists and policymakers was that some regulatory action was needed. Hexachlorophene had become an environmental contaminant in that millions of Americans carried traces of the chemical in their bloodstreams. The potential for harm was too great.

FDA proposed to limit the least important use of hexachlorophene in products that could be purchased by consumers in supermarkets and pharmacies, without preventing its most important use for medical purposes. The Agency divided hexachlorophene-containing products into three categories: drugs with small amounts of hexachlorophene; drugs with higher concentrations such as those used to bathe newborns in hospitals; and cosmetics.

For drugs containing small amounts of hexachlorophene, such as soaps advertised for deodorant use, FDA proposed that they should be marketed only with the Agency's approval. The labels of these products should contain the warning: "Caution: Contains Hexachlorophene. For external washing only. Rinse thoroughly." The purpose of this policy was to make sure that hexachlorophene is used appropriately in drugs, soaps, and other consumer products, and that consumers are advised to rinse thoroughly, lest the chemical remain on the skin and possibly enter the bloodstream.

FDA proposed that drugs with higher concentrations of hexachlorophene—that is, any product containing more than .75 percent—should be placed on a prescription basis. This would restrict their uses to situations in which they are medically necessary, as determined by a physician. FDA made clear, however, that this would in no way restrict the use of high concentrates such as pHisoHex as surgical scrubs or disinfectants in hospitals or in physicians' and dentists' offices. In fact, the Agency again advised physicians and nurses to continue to wash their hands in 3 percent hexachlorophene solutions. FDA's reasoning was that the benefits of restricting the spread of bacteria in hospitals and in physicians' offices outweighed the risk of absorbing hexachlorophene from hand washing.

FDA then turned to the use of hexachlorophene for nonessential purposes, in products with no drug use. The Agency proposed that hexachlorophene be removed from cosmetics except as a preservative in low levels, up to 0.1 percent, and then only when other suitable preservatives are not available. The effect of the policy would be to ban hexachlorophene from cosmetics as an active ingredient.

As a followup of these proposals, FDA is appointing a committee of experts to study the use of all antibacterial agents. Fortunately, hexachlorophene is only one of several drugs known to be effective against staphylococcal bacteria that cause infections. The committee will make sure that all antibacterials in over-the-counter drugs are properly used. The committee will operate as part of FDA's new program to evaluate the efficacy and labeling of all drugs sold over-the-counter without a prescription.

FDA recognizes that this program to reduce the use of hexachlorophene will force some manufacturers to reformulate their products, and is causing some concern among consumers who have been using hexachlorophene-containing products for many years without any visible ill effects.

But the scientific evidence clearly dictates the need for restrictions on hexachlorophene to protect the American consumer. FDA believes that it has no choice but to take the action it has proposed—particularly because hexachlorophene is so widely and indiscriminately used and is thought to be safe. It is clear, however, that its effects are not always evident to the naked eye but can adversely affect body chemistry and mechanisms.

It's difficult to change, but when new evidence comes along that indicates that some products may create an unwarranted hazard, then change is necessary. In the case of hexachlorophene, change in patterns of use is clearly dictated. The three studies that provided the basis for FDA's action all lead to the conclusion that unrestricted use of the chemical in consumer products and in hospital nurseries poses a potential hazard.

The hexachlorophene story is not black-and-white. As with all medications, there are real benefits to be accrued from the use of this antibacterial, but there are some real risks as well. Additional research is needed before the hexachlorophene story can be written in final form.

FDA recognizes the value of hexachlorophene as an antibacterial drug. The restrictions are designed to make sure that hexachlorophene is used appropriately and safely to protect the American consumer. FDA has initiated those restrictions in the name of the consumer, for safety's sake.

Consumers all over the Nation who support or oppose FDA's proposals to restrict use of hexachlorophene have written to FDA expressing their views.

FDA takes the opinions of consumers into consideration before it publishes a final policy order. On the next two pages are samples of letters FDA received from consumers on the hexachlorophene issue.

Wayne L. Pines is editor of FDA Papers.

CONSUMERS COMMENT ON HEXACHLOROPHENE

The announcement of FDA's proposed regulatory restrictions on hexachlorophene generated a number of letters from consumers who read about it in newspapers or magazines.

A large number of consumers cited their own personal experience with hexachlorophene-containing products and opposed any restrictions. A smaller number of writers supported the FDA position.

Here is a sampling of letters written by consumers to FDA about the hexachlorophene proposal:

From Spokane, Wash.:

"Having been informed about the toxicity of hexachlorophene, I would like to avoid products containing the substance. I know that some products do not list their ingredients, but I think for my sake and others if there is hexachlorophene in a product it should be noted on the label at least. . . ."

From Rockville, Md.:

"... It just seems to me that there is a huge inconsistency in your policy. Either all health hazards should be removed from the market or all should carry a warning, leaving the choice to the individual. . . ."

From Lima, Ohio:

"I wish hereby to protest the proposed action of the Food and Drug Administration with respect to the restrictions which they wish to impose upon the use of hexachlorophene. This antibacterial agent has withstood the test of 20-odd years use by humans with no, or negligible, adverse effects. To me this is the ultimate test of any item, food or drug, and sanctions use of the drug regardless of any abstract laboratory tests which have been performed on animals. Long-time use of it by humans outweighs anything which may be said against it. I further feel that any intrusion of the Food and Drug Administration into the use of hexachlorophene by humans is an unwarranted bit of big-brotherism on the part of the agency."

From Birmingham, Ala.:

"I have a four-month-old daughter and have used pHisoHex for her baths since birth. Needless to say, I am very concerned and would like to have any information you can furnish on the use of this product. . . ."

From Fresno, Calif.:

"I feel (hexachlorophene) should be eliminated or the concentrations of the solutions be cut down. I feel that the hexachlorophene in my deodorant is what causes my underarms to sometimes become quite tender and sensitive. I know I can't be sure that this is causing the

irritation but it sure raises questions in my mind. . . . I'd like to see some definite action taken before (hexachlorophene) becomes a major problem for society to have to solve."

From Conemaugh, Pa.:

"... I don't have your expert figures and data concerning your reasons for this action, but I do have my own years of experience with products containing hexachlorophene. We have used soap containing hexachlorophene daily in our home for more than 15 years and my daughter has used a shampoo containing hexachlorophene to control the oiliness in her hair, thus keeping the oil from her face and she does not have the problem that plagues most teenagers, acne."

From Cuyahoga Falls, Ohio:

"... I am thoroughly convinced that something must be done to prevent further misuse of this chemical in manufacturers' products. . . . As a concerned consumer I am asking you to not only warn the public of the hazards of the constant use of (hexachlorophene) products but to tighten the standards for the manufacturers. To either ban or limit its use, especially in soaps and deodorants, will, I believe, be beneficial to all of us."

From Tampa, Fla.:

"I have three sons with acne and there are probably a million parents like me. If you start requiring a prescription for pHisoHex, all I can say is, Will you pay the doctor bills?"

From Austin, Tex.:

"I would like to see hexachlorophene prohibited from use in any products, including those who do not list their contents. It would be good if the FDA could aim to protect the most ignorant of Americans, for whom a warning will not suffice. . . ."

From St. Paul, Minn.:

"Keep pHisoHex available. Placing it on Rx will lessen its proper use and increase the spread of serious infection."

From Sagamore Hills, Ohio:

"PHisoHex should not be placed on a prescription basis. PHisoHex is safe in all of its many years that I have been using it. Great harm will probably come from placing this good product on prescription."

From Sacramento, Calif.:

"We have used and sold pHisoHex for many years without any complaints or side effects. We strongly oppose putting pHisoHex on a prescription basis as this would increase the cost to the consumer and cause inconvenience to the patient and practitioner. The advantage of controlling infection far outweighs the possible side effects in our opinion."

From Ann Arbor, Mich.:

"... Congratulations on informing the public about hexachlorophene. I will be very happy if they stop putting it in cosmetics. Back in the '50's I went to several skin specialists to try to find out why my hands were broken out and bleeding. In the past few years lipsticks have burned my lips so that skin peeled off. Some hand lotions make my hands burn and lately face creams have been making my face break out. I decided several years ago that hexachlorophene was at the bottom of my problems and have been trying to avoid it whenever possible, but many things aren't labeled. I have no other allergies so I have never felt my skin was extra-sensitive. Thank you for your work in this area."

From Buena Park, Calif.:

"... I (am) disturbed by the effects hexachlorophene can have on the human body and in experimental rats. ... My brother and I are managing our father's store so that he can go to college. ... We have proceeded to clear our sundries shelves of all those products which contain hexachlorophene (and are used bodily) as well as those who do not list the ingredients. ... We hope this action in some small way will stimulate the various industries—soap, cosmetics, etc.—to comply with the FDA request. If they won't then perhaps further regulations by your agency will be necessary. ..."

From University Heights, Ohio:

"I am a purchaser of the product pHisoHex. My two children use it every day. They like the results and we continue to buy it regardless of what we have heard and read. ..."

From Metairie, La.:

"I have ten grandchildren—and pHisoHex has been used for all of them. Some of them are teenagers now, and they are still using it for skin infections, etc. ... Please do not let this item become a prescription one—the cost of living is too high already."

From Alachua, Fla.:

"... My daughter has used this product (pHisoHex) for a shampoo and hand soap for many years with no ill effects. We are in the horse training business and have used it quite extensively both in the barns as a wound treatment (cleansing) and to prevent human infection. In the last fifteen years I cannot recall a single infection in the family. We feel that this is the one over-the-counter antibacterial agent we can get which really does the job."

From North Randall, Ohio:

"It comes as quite a surprise to me that pHisoHex is being considered to be sold on a prescription basis. I have been using pHisoHex since I was a teen-ager, along with many of my friends, and I have never suffered any adverse effects. Along with teens and babies everywhere, I hope that the committee involved will reconsider and not classify pHisoHex as a prescription drug."

From Wrightsville Beach, N.C.:

"I would like to urge strongly that more research be done on products. The cost of one human life is too high a cost and in no way comparable to quick profits, or any monetary gains from rapid marketability of new developments."

From Everett, Mass.:

"I am writing regarding what I am reading in the papers about hexachlorophene (HCP). Just before notice of the drug appeared in the papers I had purchased at a reduced price (to wit, 10¢ a cake in place of 18¢ per cake) 24 cakes of this soap. I am reluctant now to use same, but it is still being displayed for sale in the Chain Stores. I find it very drying."

"Will you please advise me whether to discontinue using same or whether it is safe?"

From Scottsdale, Ariz.:

"I am writing in strong support of your recent proposal to prohibit the use of hexachlorophene in cosmetics until adequate safety tests have been made, to restrict in other products, and to require that they carry a warning statement."

"Although the amounts of hexachlorophene ingested in antibacterial cleansers, shampoos, and other cosmetics may not be enough to cause brain damage within themselves, when they are added to other chemicals in the air, water, and foodstuffs, they present an unknown hazard to humans."

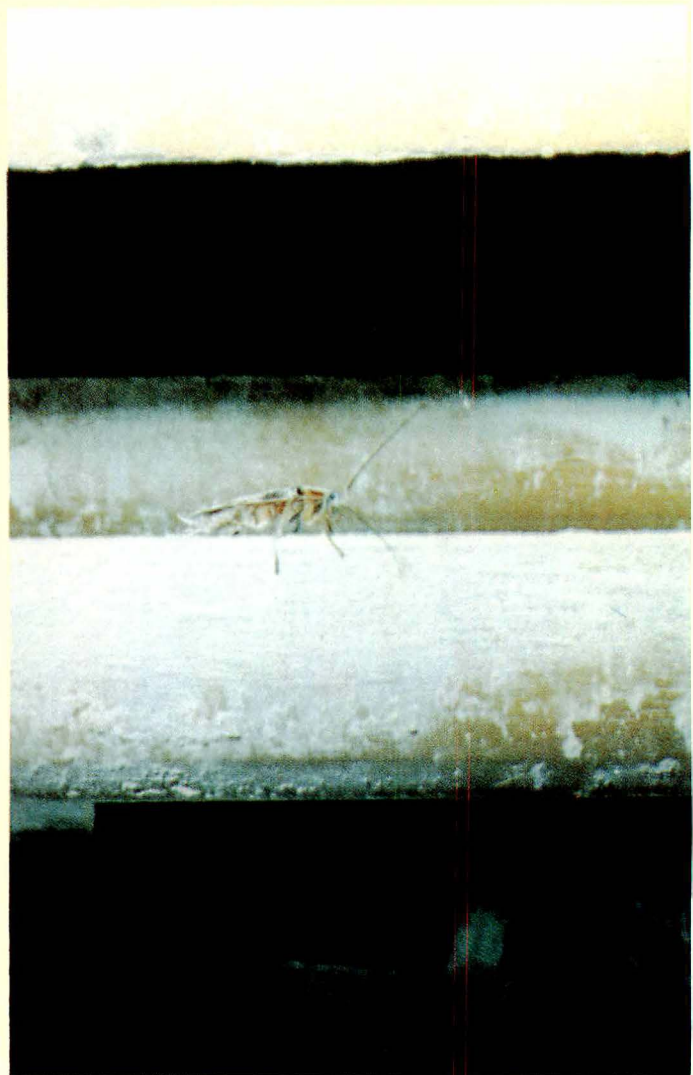
"Hexachlorophene should be prohibited at least until adequate tests of its long and short range effects have been made by scientists working independently of manufacturers and receiving their pay from independent agencies. This is of the utmost importance to avoid unintentional bias."

Spotting Trouble When It Counts



A policeman walking his beat often deals with unpleasant sights and subjects never encountered by the public. So it is with FDA food and drug inspectors and other experts doing their jobs in the field. They duly note violations or failures to comply with regulations, and how they may compromise the protection owed to the consumer. Because the finished product may provide no easily recognized clue as to whether a violation has occurred, it is up to the trained FDA inspector, microbiologist, chemist, or product safety expert to identify violations that should be corrected before the product reaches the consumer. On this and the following pages are shown some violative products or practices encountered by FDA experts in their front-line task of surveillance in behalf of the public health and well-being.

A candy plant employee working at a filling machine was smoking a cigaret when he saw an FDA inspector coming and hurriedly stubbed out his cigaret (right in photo) on the machine. Besides falling cigaret ash, the cigaret itself might have found its way into packaged candy.



A consumer complaint to an FDA District about insects in dry foods bought at a supermarket resulted in an investigation disclosing that almost all the products in one aisle—including rice, beans, split peas, macaroni products, and packaged dinners—were infested with sawtooth beetles and confused flour beetles. The store voluntarily destroyed 1,900 pounds of infested foods. Here sawtooth beetles attack a package of rice.

During inspection of a bakery, two inspectors noted hundreds of cockroaches, live flour beetles and larvae, mouse excreta pellets, and rodent entryways providing access to the plant. Here a cockroach almost three inches long perches on dough processing equipment.



The opening of an inspection port under a rotating flour sifter in a flour mill revealed this heavy growth of mold and mold fibers.



The paint on this child's chair, upon analysis, was found to contain lead, a toxic substance, in excess of FDA's action guidelines. The ease with which a small and curious child could pick off and eat the paint containing this poison is shown by the flaking of the paint at left and right in this close-up photo of the chair's back.

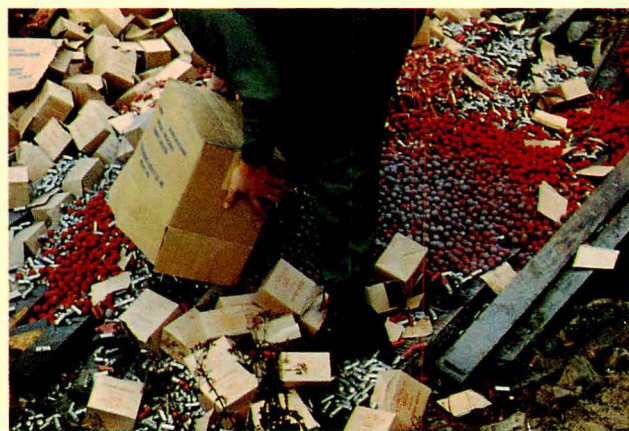


Rodent teeth marks on packaged cream cheese were discovered during an inspection of a large wholesale grocery warehouse. The inspector also found rodent excreta pellets in the vicinity of the stored product.



This collection of "squeeze toys" have one other thing in common besides the name.

They have small whistles or squawkers (shown near each) that are easy for a small child to detach and put in his mouth, from where they might be swallowed and lodge in his throat, causing suffocation. They're on FDA's list of banned toys.



Army personnel help destroy this large haul of illegal fireworks by exploding them in a stone quarry. FDA action brought about seizure of the lot of 310,000 units, consisting of M-80s, Silver Salutes, and Cherry Bombs, all banned as hazardous substances.



In a plant that processes butter, an employee uses his bare hand to smooth down crumbs of butter loosened by cutting wires from a large block of butter in bulk form. His other hand rests on his soiled workclothes, where he apparently has been wiping his hands after such food handling.



This is the way part of a ship's cargo of 10,000 cartons of canned pineapple, oranges, bamboo shoots, and other oriental foods looked after passing through a storm at sea that caused both water and other physical damage to the shipment. The goods were detained upon arrival and the damaged goods segregated for destruction.

This nest of eight live young mice was turned up among bags of cat food during inspection of a warehouse.

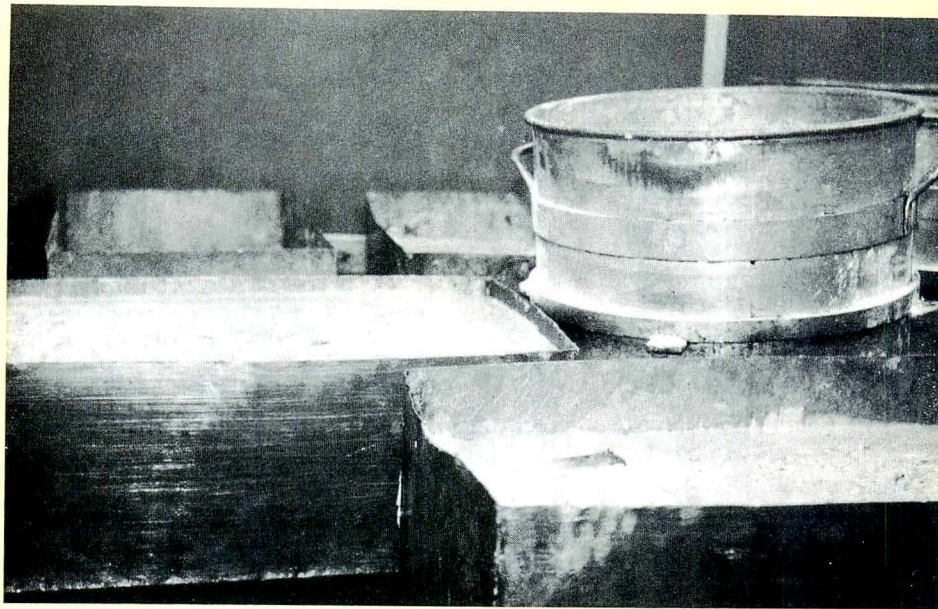


A food warehouse was found to be infested with both rodents and birds during an inspection. Here a bird in midair feeds from a bag of rice.

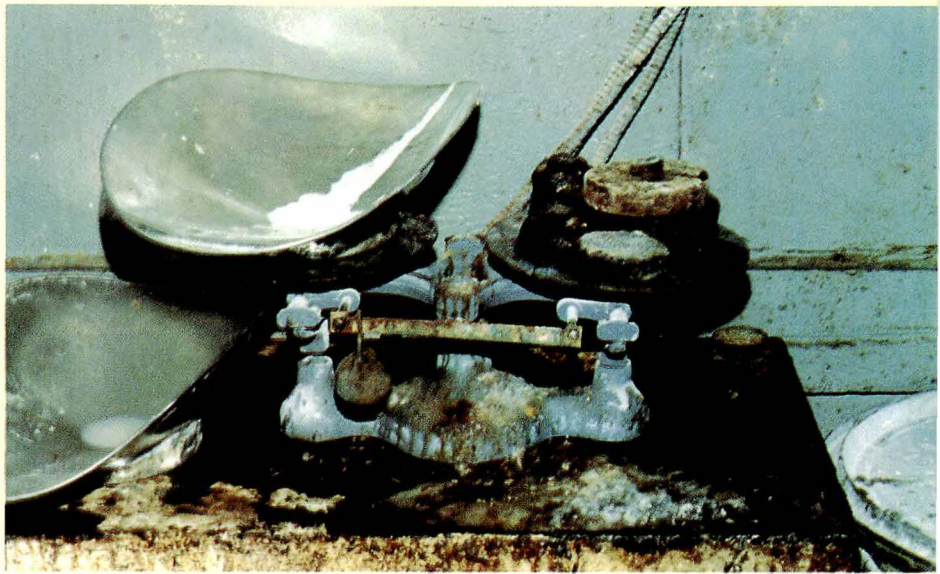
General disarray in both production and storage areas was noted during an inspection of the premises of a small drug repacker and medical device distributor. Here is shown the disorganization of the device storage area along with miscellaneous unrelated equipment and articles.



In a corn and flour milling plant a live mouse gnaws at a bag of cornmeal. Four other live mice were spotted around the plant.

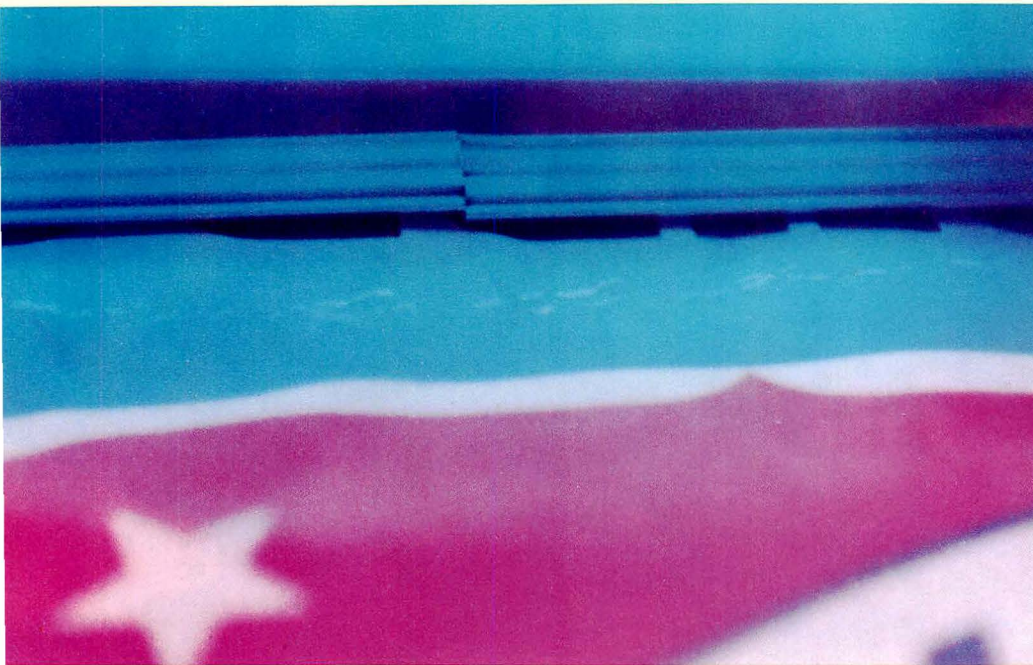
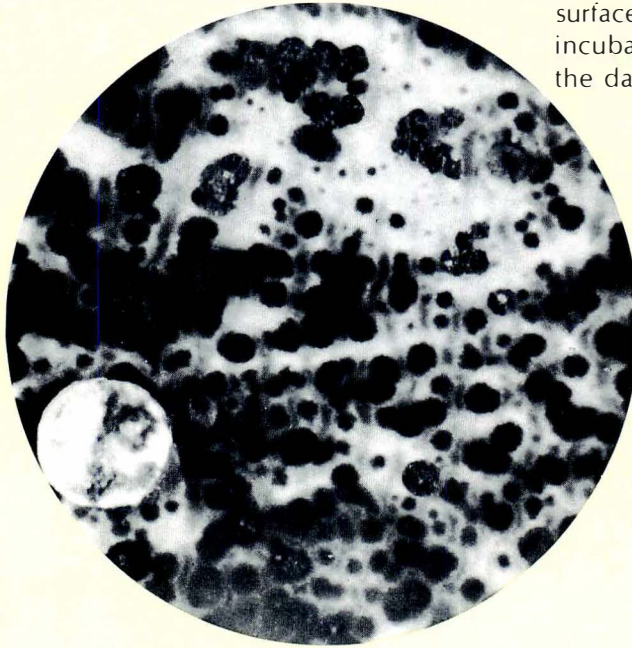


In a candy-making plant, the inspector found a total of seven uncovered tubs of peanut butter and six partly uncovered tubs. Those shown reportedly had remained uncovered since the previous day.



This scale, used in a bakery to weigh ingredients, is encrusted with decomposing dough and other filth in violation of good manufacturing practices.

The white sulfathalidine tablet at lower left on the plate was found to be contaminated with molds, including *Penicillium* and *Aspergillus* species, after being moved aseptically over the surface of the agar plate and the latter incubated for five days at 25° C. All the dark spots are molds.



Rodent urine stains were found on a bag of flour during a warehouse inspection through the use of ultraviolet light. Here the stains, under UV light, appear on the bag as white spots across the center of the picture.

Inspection of a large potato chip processing plant turned up this evidence of rodent defilement of bags of a dehydrated specialty potato food. Shown here are the strewn product, rodent excreta pellets, and urine stains.

news highlights

Final Order Issued for Child-Resistant Petroleum Distillate Furniture Polishes

A final order requiring "child-resistant" safety packaging for liquid furniture polishes containing 10 percent or more of petroleum distillates has been published by FDA. It becomes effective 180 days from its publication in the *Federal Register* March 17.

The order is intended to protect children under five years of age from accidental ingestion and aspiration of low viscosity petroleum distillate polishes. These result in chemical pneumonitis and are a significant cause of hospitalization and fatalities.

Furniture polishes are the second class of products required by FDA to be marketed in special packaging under the provisions of the Poison Prevention Packaging Act. Final orders for aspirin and aspirin preparations were promulgated February 15. Final regulations for oil of wintergreen liniments and certain drugs are to be published.

Safety standards for the package require 85 percent closure effectiveness against the efforts of a test group of 200 children. The regulation also specifies that the special packaging restrict the flow of the liquid so that not more than two milliliters of the contents can be obtained when the inverted opened container is shaken or squeezed once or when the container is otherwise activated once.

Of the 35 comments received from consumers, clergy, medical and academic communities, trade associations, the packaging industry, and manufacturers, 25 supported the proposal.

Child-Resistant Packaging Proposed For Unbanned 2-10% Caustic Products

FDA has proposed a regulation to require that household products containing sodium or potassium hydroxide be marketed in child-resistant packages. The proposal was published in the *Federal Register* March 9.

Sodium or potassium hydroxide or both are found in a number of household products such as lye, oven cleaners, and some drain and toilet bowl cleaners. The corrosive action of these caustic substances on the eyes, mouth, esophagus, and stomach has been a significant cause of hospitalizations and fatalities of children under five years of age.

Reports from FDA's National Clearinghouse for Poison Control Centers for the period 1968 through 1970 show 1,661 ingestions of these products by children under five. Of these, 609 children were hospitalized. Data from death certificates show that seven children died during this same period through accidental ingestion

of products containing more than 10 percent sodium or potassium hydroxide.

The FDA proposal on child-resistant packaging, proposed under the Poison Prevention Packaging Act, would require such packaging for all liquid products containing between 2 and 10 percent sodium or potassium hydroxide. The ban remains in effect for liquid products with more than 10 percent of the toxic substances unless they are in child-resistant packaging.

As specified by the Poison Prevention Packaging Act, each manufacturer of liquid products will be permitted one exempt product size for use in households without children. The banning action in 1971 does not permit an exempt product size for liquid products containing more than 10 percent of the toxic substances.

The proposal would also require that products containing 10 percent or more of one or both of these toxic chemicals in nonliquid form be packaged in safety packages with one exempt package size for each manufacturer. Products in this form have been judged less hazardous.

The safety standards for special packaging for these products must conform with FDA's testing protocol which requires 85 percent closure effectiveness in tests with a specified group of 200 children.



Order Issued to Phase Out Use of Lead In Household Paints by End of 1973

A final order banning lead from all household paint has been issued by FDA.

Charles C. Edwards, M.D., Commissioner of Food and Drugs, said the order is intended to reduce, as soon as technically feasible, the amount of lead to which children may be exposed.

"Although paints containing lead do not present an imminent hazard to the public health, they must be considered on the basis of cumulative toxicity over extended periods of time and in conjunction with other sources of lead in the environment," Commissioner Edwards said.

"Regulatory action must be taken to minimize the health hazard to future generations. This regulation is designed to accomplish this purpose."

The regulation, published in the *Federal Register* March 11, will prohibit the shipment in interstate commerce of paints and similar surface coating materials, intended for use in or around the household, containing more than 0.06 percent levels (essentially trace amounts) of lead. The order will take effect December 31, 1973. As an interim measure, beginning December 31, 1972, the order bans from interstate shipment all paints containing more than 0.5 percent levels of lead.

The regulation also bans toys and other articles intended for use by children which bear paints or other similar surface coating materials with levels of lead above the limits set forth in this regulation.

Both bans are being ordered by FDA under the provisions of the Federal Hazardous Substances Act.

Two proposals to limit the amount of lead in paint were published for public comment in the *Federal Register* on November 2, 1970. The first proposal would have set the allowable lead limit in paint at 0.5 percent. The second proposal, sponsored by Joseph A. Page and a group of citizen petitioners, requested that only minute trace amounts of lead be allowed in paint.

Approximately 200 comments were received from consumers, consumer and public interest groups, the paint and chemical industries, trade associations, physicians, medical schools, professional societies, Federal, State, and local government agencies, and others.

Comments by the medical profession, in general, agreed with the American Academy of Pediatrics, which had recommended that all paints containing more than 0.06 percent of lead be banned if intended for use on interior surfaces, toys, or other children's articles.

FDA Proposes Comprehensive Regulations To Keep Food Supply Free of PCB's

Comprehensive regulations intended to limit human exposure to PCB's (polychlorinated biphenyls) from

foods, have been proposed by FDA.

In announcing the proposed regulations, Charles C. Edwards, M.D., Commissioner of Food and Drugs, said that although it is not possible for FDA to remove PCB's from the environment, the Agency can and is taking all steps within its authority to limit exposure from foods. The proposed regulations were published in the *Federal Register* March 18.

"We do not believe that current food levels present a hazard to public health," said Dr. Edwards. "We do believe, however, that the sources of PCB's in foods can and should be significantly reduced to prevent any potential hazard from developing."

FDA's proposal would deal with known problem areas by:

1. Eliminating all sources of direct, accidental PCB contamination during the handling, processing, and storage of feed, food, and packaging material.

2. Prohibiting from the recycling process, deliberate or avoidable inclusion of pulp that contains any poisonous or deleterious substances which might migrate to food.

3. Setting temporary tolerances for a sufficient period of time for unavoidable PCB residues in food packaging materials and certain foods. Such tolerances are being set because it is not possible at this time to totally eliminate PCB's caused by environmental or industrial contamination.

PCB's have been produced since 1929 and have had a wide range of uses. The substances have been or are being used as heat exchange liquids, as dielectrics, in lubricants and hydraulic fluids, and as ingredients in paints, plastics, resins, inks, waxes, adhesives, rubber, asphalt, and various building materials. This widespread usage, combined with the highly stable and persistent qualities of the substances, have resulted in the occasional appearance of PCB's in the food supply.

FDA's investigation into the incidence of PCB's in foods has shown:

- Except for avoidable industrial accidents and practices, PCB contamination of animal feeds is not a significant problem.
- PCB's were found in 67 percent of food packaging tested by FDA. They were found in both recycled paper and virgin stock. However, only 19 percent of the foods in these packages contained PCB's, with an average concentration of 0.1 parts per million. Subsequent surveys show a continuing and substantial reduction of PCB's in packaging material.
- Investigations show the presence of PCB residues in freshwater fish and in some food animals. The source of these residues is attributed in part to environmental contamination, such as discharges of PCB waste effluents into water and air.

Although additional research is needed to determine the effects of low level human exposure to PCB's over a long period of time, the FDA action is being taken as a precautionary measure to eliminate any unnecessary exposure.

Trade Groups Agree to FDA Request To Improve Extension Cord Safety

The National Electrical Manufacturers Association and Underwriters Laboratories have agreed to improve safety features of household extension cords, FDA announced.

Investigations of 107 burn cases conducted by an FDA injury study unit of the Bureau of Product Safety indicated that redesign of extension cords is needed to safeguard children from burns and injuries.

The injury data was provided to the industry, which has subsequently notified FDA that it is now taking steps to improve the design of extension cord connections to prevent them from being pulled apart easily and to prevent any portion of the prongs from shocking a child.

The multiple outlet extension cord is being studied for possible redesign so that unused outlets will be protected from small children. Addition of warning statements on extension cords advising that they be removed from wall sockets when not in use is also being considered.

Soluble Cyanide Salts Banned by FDA As Too Dangerous in Household Products

Household products containing soluble cyanide salts have been banned as hazardous substances by FDA. The Agency said the rapid fatal effect of accidental ingestion of a soluble product containing cyanide virtually precludes any first-aid treatment. Products FDA has identified on the market today as being affected by the banning order include Silveron Pure Silverplate, Re-Silvering Polish, and AG-25 Pure Silver Plate. The final regulation was published in the *Federal Register* March 7 to become effective in 45 days.

Results of Antacid, Analgesic Study Published

FDA has published results of a National Academy of Sciences/National Research Council review of effectiveness claims for 18 antacid and 14 pain relieving and antifever drugs.

The report on antacid products cited 27 claims made for the 18 products. Four claims were judged by NAS/NRC panels as "effective," one as "ineffective." All other claims were judged "possibly" or "probably" effective on the basis of available scientific data.

The report on analgesic products cited 24 claims made for the 14 products. Two claims were judged by NAS/NRC panels as "effective," one claim "probably effective," two "possibly effective," and two "ineffective." Other claims were judged effective but with certain reservations.

Under NAS/NRC classification, "probably" effective

signifies that for a particular claim, the available evidence indicates the drug probably accomplishes its proposed effect, but that additional evidence is required before the drug can be deemed effective beyond reasonable doubt. "Possibly" effective means that evidence of effectiveness for a given indication might be developed, but to date is not available.

The 32 antacid and analgesic drugs were among 420 representative over-the-counter (OTC) products studied at FDA's request by the NAS/NRC.



FDA to Halt Use of Small Oxygen Tanks As Inadequate in First Aid Treatment

FDA has proposed to halt the sale of pocket-size and other miniature containers of oxygen that have been sold for first aid treatment of serious conditions such as heart attacks, emphysema, and asthma.

Many of the containers do not have enough of oxygen to be suitable for any medical or emergency use, according to FDA. In the past a claim for use of the small containers was permitted for motion sickness. This use is now considered by FDA as irrational.

Since 1953, oxygen for emergency medical use has been considered by FDA as suitable for sale without a prescription. FDA's concern in today's proposal is not the oxygen, but the pocket size and similar devices for delivering it to the user.

Under the new policy proposed in the *Federal Register* March 16, emergency oxygen administration units would consist of the following items:

- a portable oxygen container holding medical grade oxygen (USP);
- a dispensing device consisting of pressure reducing equipment capable of maintaining a constant flow of at least 6 liters of oxygen per minute for a minimum of 15 minutes;
- a content indicator; and
- a mask or other means of administering the oxygen to the patient.

field reports

ATLANTA An animal feed firm in Birmingham notified the Atlanta Field Office that it has voluntarily destroyed approximately 431,000 pounds of hominy feed and 250,000 pounds of white corn that FDA found in a recent inspection was high in aflatoxin content, a toxin produced by the growth of the mold, *Aspergillus flavus*. Destruction was carried out by burying the products in a local landfill.

Over 9,000 persons attended the Southeastern-International Educational Poultry Convention at the Atlanta Civic Center, where Dr. James D. Kornder, FDA regional veterinary medical officer, manned the Atlanta Field Office exhibit. Jack Taylor, Bureau of Veterinary Medicine, was there to speak on FDA's present policy on the question of recycling and using poultry litter in animal feed. At this time, the Agency does not sanction its use. As part of the exhibit, FDA PAPERS was promoted as an informative resource for industry.

BALTIMORE FDA has fulfilled the formal training provisions in its comprehensive agreement with the Food Section of the Virginia Department of Agriculture and Commerce (see FDA PAPERS, May 1971 issue). Donald O'Connell, assistant supervisor of the State section, attended FDA's training course for bacteriological inspections held March 12-24 at the University of Wisconsin in Madison. He occupied the first slot designated by FDA for State officials. The Agency pays the tuition costs.

BOSTON Recent FDA import detentions at the port of Boston included canned mango pulp, rice jelly, and Irish moss that did not comply with the Fair Packaging and Labeling Act; macaroni, apricot paste, and toasted corn farina infested with insects; emperor snapper fillets containing mercury above the FDA guideline; a sugar almond product with peanuts substituted for almonds; canned shrimp that was decomposed; and colored toy sisal monkeys that FDA has banned as hazardous.

Included in the recent programs sponsored by the Field Office for senior citizens were two on health fraud presented by Yolán Harsanyi, consumer specialist, to the Council of Elders from the Neighborhood House in Roxbury, Massachusetts. Miss Harsanyi also conducted a training workshop at Cape Cod for volunteers in the American Association of Retired Persons and the National Retired Teachers Association. The two groups are sponsoring a series of consumer information desks to assist in resolving consumer problems. The workshop was aimed at interpreting FDA's regulations and telling how the Agency works for the consumer. A sec-

ond workshop of the same type and held for the same reason was presented in Portland, Maine, by Frank Scholl, FDA's resident inspector there.

Miss Harsanyi also was a guest speaker at a consumer education workshop sponsored recently by the Connecticut Coordinating Council for Consumer Affairs. She spoke about FDA's nutritional guidelines for certain classes of foods. Among the State officials participating in the workshop was Eaton Smith, chief of the Foods Division, Connecticut State Department of Consumer Protection.

Robert Kilpatrick, regional product safety consultant, recently conducted a series of talks on toy safety and flammable fabrics to the kindergarten through grade 6 classes in the Arlington, Massachusetts, public schools. During a period of three weeks, he addressed 5,000 children and teachers.

BUFFALO P & C Food Markets, Inc., Syracuse, New York, was fined \$500 each on two counts of a three-count information charging storage of foods under conditions whereby they were contaminated by rodent filth after receipt in interstate commerce. The third count of the information against the firm and charges against an individual were dismissed. The judge reportedly remarked before sentencing that it was unfortunate the firm had not undertaken to make needed corrections on its own without regulatory action.

Following seizure of hairbrushes valued at \$17,757 at the Mohawk Brush Co., Division of Fuller Brush Co., Albany, New York, because the articles contained nits and nit fragments, the firm indicated that it would file a claim for the goods and that reconditioning is proposed. The bristles used in the brushes were imported from India.

District representatives witnessed the recent voluntary destruction by Gioia Macaroni Co., at Buffalo, of 112,416 six-ounce cans of Heritage House Brand tomato paste valued at \$7,870. The lot was destroyed because it contained a large number of cans that were abnormal due to an apparent reaction with the metal in the container. The firm had imported the product from Portugal.

CINCINNATI A nutritional labeling experiment is being conducted locally by one of the major food chains in cooperation with the FDA. The pilot study started January 31 and was to be continued for three months. It involves a limited number of food products marketed by the Kroger Co., Cincinnati. FDA's purpose for the nutrient labeling is an attempt to use food labels to

make consumers aware of the nutrients that are in the food they purchase and to help them select a nutritious diet.

Recalls are being initiated on promotional bowls prepared by Americana Art China Co., Sebring, Ohio, for a cereal firm and a soup firm. The District's recent analysis of bowls with nine decals promoting cereals for National Biscuit Co., New York, and shipped by the Ohio firm, revealed 51.5 to 79.2 parts per million of leachable lead, with an average of 69.2 ppm; and 9.0 to 12.3 ppm of cadmium, with an average of 10.4 ppm. The bowls were promoted on the boxtops of Nabisco's Cream of Wheat cereal, with customers placing orders for individual units directly to the china firm in Ohio.

A lot of similar promotional bowls prepared by the china firm for the Campbell Soup Co., Camden, New Jersey, is also being recalled.

DALLAS The Division of Veterinary Public Health of the Texas State Department of Health is now the third unit of the triad combating *Salmonella* in animal by-products for feed. The U.S. Department of Agriculture referred 23 rendering plants to the Dallas District because the plants did not wish to enter the voluntary program. District inspections showed no interstate business. Therefore, correction was attempted by a warning letter and a report of analysis. Copies of the letter were sent to the State agency also, and the Division of Veterinary Public Health responded with a letter saying that since it licensed such plants, it felt responsible for assuring that only *Salmonella*-free products left the plants. The Division asked for help from the Dallas District in identifying problem areas and promised corrective action. Two plants have been referred to the State Division, and the District veterinarian has planned a meeting in Austin with the State personnel.

DETROIT FDA and officials of Pillsbury Co. signed a self-certification agreement in Terre Haute, Indiana, which provides that the firm's Terre Haute plant will utilize comprehensive quality assurance monitoring systems. In effect, the firm will be involved in increased self-regulation, which should provide more protection for the consumer.

Pillsbury's Terre Haute operation is the first plant in FDA's Detroit District to engage in the Agency's Self-Certification Program. Products manufactured at the plant include food sticks, frosting, sauce mixes, color premixes, flavors, and instant breakfast.

The agreement, which was effective on February 15, states that Pillsbury officials will police their own prod-

ucts and make periodic reports to both State and Federal officials. Those signing the agreement were Alan L. Hoeting, deputy regional food and drug director at FDA's Detroit District; Robert L. DeMunck, manager of Pillsbury's Terre Haute operations; Raymond Kimsey, vice president and general manager of the Grocery Division, Pillsbury Co., Minneapolis; and Frank E. Fisher, director of the Bureau of Foods and Drugs of the Indiana State Board of Health.

KANSAS CITY Theodore O. Perlenfein and his wife, Edna L., trading as Ted's Tobacco and Grocery Store, Tarkio, Missouri, were fined a total of \$500 recently by Calvin K. Hamilton, U.S. Magistrate, Western District of Missouri, after the couple pleaded guilty to a charge of selling Cherry Bombs and M-80 firecrackers, banned hazardous substances, to an undercover agent of the FDA on June 23, 1971, in Tarkio.

Lorena Meyers, Field Office consumer specialist, has been providing workshops for the past two years for 13 classes of student practical nurses from eight area hospitals, totaling approximately 300 practical nurses annually. The program originated when Genevieve Duncan, general coordinator for health occupation of the Board of Education, Kansas City, accompanied a tour of student practical nurses at FDA's Kansas City facilities. Impressed by the nature of the informational material provided, Mrs. Duncan suggested that each hospital arrange for a workshop during the year's training. As a result, an FDA tour and lecture augmenting the classroom program is now included annually in the local Kansas City practical nursing curriculum.

The practical nurses' course includes study of laws covering safety of foods, drugs, health devices, and the safe use of hazardous substances. The additional FDA workshop training provides a better understanding of drug controls, reactions from hazardous substances, bacteriological contamination of foods, and prevention of injuries caused by consumer products.

LOS ANGELES As a follow-up to a previous seizure of the same product, District inspectors examined another lot of canned Spanish artichoke hearts under the Reese Finer Foods company label at the firm's Los Angeles premises. As before, the products were seized because of swelled cans and progressive decomposition. There appears to be a possibility of a general problem with this commodity, for this was a different lot and had been shipped from Chicago by a distributor other than that of the first seized lot.

Since the District's trailer laboratory operation began

January 10 at the Mexican border in Nogales, Arizona, a total of 118 samples of imported vegetables have been analyzed. Among them were nine Mexican squash samples found to contain over the tolerance level of endrin, an agricultural pesticide. All lots sampled originated from the same 200 acres in Mexico. As a result, the detained shipments are being destroyed, and the importer is stopping further importation.

MINNEAPOLIS FDA's three-count prosecution against Security Wholesale Grocery Co., Inc., St. Paul, and the firm's secretary-general manager, Maurice C. Manton, Sr., has been terminated with conviction on one count and dismissal of the other two. The defendants entered a plea of guilty January 17 to the first of three counts charging the storage of infested foods in an insect-infested warehouse after receipt of the foods in interstate commerce. Chief District Judge Edward J. Devitt of the U.S. District Court at St. Paul fined the firm \$3,000 on the first count and placed the individual on probation for one year with the provision that both cease business by April 15. The other two counts were dismissed. The assistant U.S. attorney had proceeded by indictment, since the same firm and individual were prosecuted for similar offenses in 1958.

NEW ORLEANS Recent District detentions included \$6,252 worth of romano cheese containing the insecticide benzene hexachloride, \$128 worth of camembert cheese in violation of the Fair Packaging and Labeling Act, \$1,040 worth of toys in violation of the Federal Hazardous Substances Act, and a \$10,291 shipment of insect-infested wheat gluten.

The District also ordered seizure of 332,000 pounds of corn worth \$7,500, contaminated with aflatoxin, a toxin produced by growth of the mold, *Aspergillus flavus*; moldy fruit cocktail worth \$914; and highly inflammable plastic dolls worth \$1,970.

NEW YORK Kenneth Silver, director of education and information for Region II, acted as chairman of a meeting of consumer protection officials in Paterson, New Jersey, at the request of Raymond Behrman, director of consumer affairs for the city of Paterson. Mr. Silver functioned as chairman of the New Jersey Federal Executive Board's Committee on Communicating with the Disadvantaged. This leadership group has voiced concern about the need to bring together the various agencies in the city involved with consumer protection. Accordingly, the members appointed themselves as a steering committee for the establishment of the Paterson Consumer Affairs Committee on which Fed-

eral, State, municipal, and private organizations would be represented. At the same time, they noted the need for citizen input and planned to form a citizen's advisory committee, representing the full spectrum of the community, in the near future.

Mr. Behrman was appointed chairman pro tem of the advisory committee; Ruth Ballou, assistant director of the New Jersey Division of Consumer Affairs, was asked to serve as liaison with State organizations; and Mr. Silver was asked to serve ex officio for liaison with Federal organizations.

After reviewing an advertisement in a newspaper in New Brunswick, New Jersey, for sale of a Relaxacizor device, an FDA inspector visited the woman who placed the ad. He gave her a copy of the FDA fact sheet describing the dangers of the device and informed her that the device could not be sold legally. After reading the fact sheet, the woman voluntarily destroyed the device.

SAN FRANCISCO Among the 60 detentions of commercial entries of various food, drug, and cosmetic products made by the District recently were two lots of fish containing mercury about which the District had been alerted. Approximately two months before the fish arrived, Canadian authorities advised the District that two separate lots of canned fried fish products manufactured in the People's Republic of China had been sampled and analyzed when they arrived in Canada and were found to contain excessive amounts of mercury. They said also that the Canadian importer was reexporting the fish to two San Francisco consignees. On arrival of the lots, samples were drawn and District analysis confirmed the Canadian findings. Detentions were issued and the lots were subsequently refused admission.

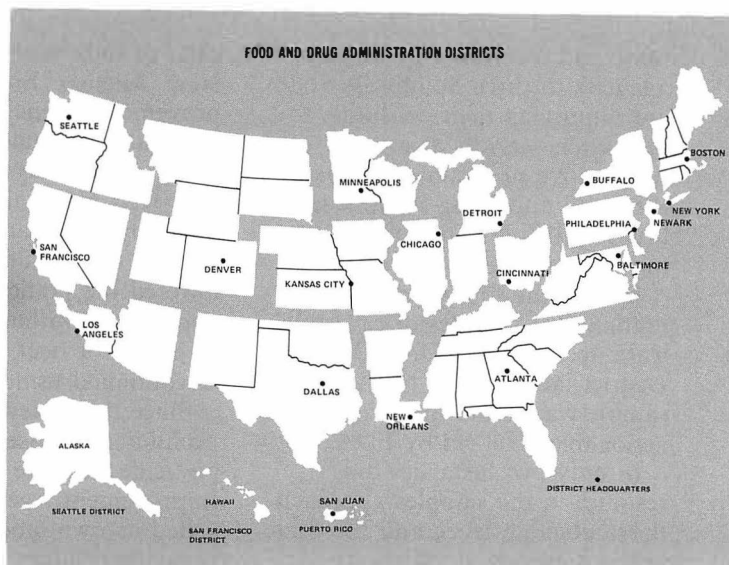
Following a District inspection at Marbo Quality Foods, Inc., Fresno, California, a lot of 58 hundred-pound bags of cranberry beans, valued at \$667, was taken into custody by a U.S. marshal on charges the product was contaminated with rodent urine and was held under insanitary conditions whereby it may have been contaminated with filth. Complaints and requests for action have been forwarded to the U.S. attorney's office involving three other lots of foodstuffs in possession of the same firm.

SEATTLE Recycling glass is a continuing project for 65 members, 10 to 18 years of age, of the Junior Drill Team of the Fraternal Order of Eagles at Ballard, Washington. When one of the team members read in a

newspaper that 8,631 cases of soft drinks and 166 one-gallon jugs of beverage syrups containing cyclamates had been seized by order of FDA and were to be destroyed, the team decided to contact the U.S. marshal who had seized the products and request permission to salvage the glass.

The team wrote a proposal explaining how its members would destroy the product and salvage not only the glass bottles but also the cardboard and wooden cases and bottle caps. The Federal Judge who had ordered the products destroyed amended the destruction order to allow the team to carry out its proposal.

Team members, parents, and others spent 800 man-hours opening bottles, dumping contents, and sorting glass which they sold at one cent a pound for a total of \$629.10. They donated 1,500 pounds of cardboard to a paper drive, returned the wooden cases to the beverage company for a refund, and donated the bottle caps to an elementary school class that was collecting such caps.



FDA REGIONAL AND DISTRICT OFFICES

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

BALTIMORE 900 Madison Ave.
Baltimore, Md. 21201

BOSTON 585 Commercial St.
Boston, Mass. 02109

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

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

CINCINNATI 1141 Central Pkwy.
Cincinnati, Ohio 45202

DALLAS 3032 Bryan St.
Dallas, Tex. 75204

DENVER New Customhouse Bldg.
Rm. 513/20th & California Sts.
Denver, Colo. 80202

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

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

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

MINNEAPOLIS 240 Hennepin Ave.
Minneapolis, Minn. 55401

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

NEW YORK 850 3rd Ave.
Brooklyn, N.Y. 11232

NEWARK Rm. 831, 970 Broad St.
Newark, N.J. 07102

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

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

SAN JUAN P.O. Box 4427
San Juan Station, P.R. 00905

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

NEW REGIONAL OFFICES I-X

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

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

PHILADELPHIA 401 North Broad St.
Philadelphia, Pa. 19108

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

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

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

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

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

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

SEATTLE Arcade Plaza Bldg.
1321 2nd Ave., Seattle, Wash. 98101

KEEPING MILK FREE OF PESTICIDES

by Robert E. Adams

State and local milk regulatory agencies in three Southwest States are improving their consumer protection services as a result of a cooperative program developed by the Food and Drug Administration's Dallas regional office to test raw milk for pesticide residues.

During the first year of operation, 223 samples of raw milk were analyzed at FDA's Dallas District laboratories. Not a single sample was found to be above the actionable level set by FDA.

In only two instances did residues in the samples approach the actionable level, and the State authorities moved swiftly to identify the problem and reach a solution. These cases involved milk with a relatively high contamination rate that came from eastern New Mexico.

An investigation by Tom Proctor,

chief of milk sanitation for the New Mexico Environmental Improvement Agency, implicated DDT and its analog DDE in locally grown alfalfa hay and in cottonseed feed materials shipped from a nearby Texas area. Discontinuation of the use of these feeds lowered the pesticide levels appreciably within 90 days. Area feed lots for beef animals also discontinued using these feeds.

Since then, New Mexico has prohibited the use of DDT as a pesticide, and the Environmental Improvement Agency has established its own laboratory where pesticide residues tests can be conducted.

In addition to New Mexico, the program involves the States of Oklahoma and Texas. They test milk under milk sanitation regulations identical to the 1965 Grade

"A" Pasteurized Milk Ordinance, which is recommended by FDA.

The program began more than a year ago, when the Special Programs Branch of FDA Region VI in Dallas asked the milk regulatory agencies in the three States whether they wanted to participate in the cooperative testing program. More than 90 percent said they did.

Health agencies near the District laboratory bring samples of two one-quart glass containers directly to the lab. Outlying areas ship the refrigerated samples by bus to Dallas. Assay results are furnished to both the agency supplying the milk and the State regulatory agency.

The program will be extended to the entire region, and areas that did not become involved in the program during the first year are expected to join.



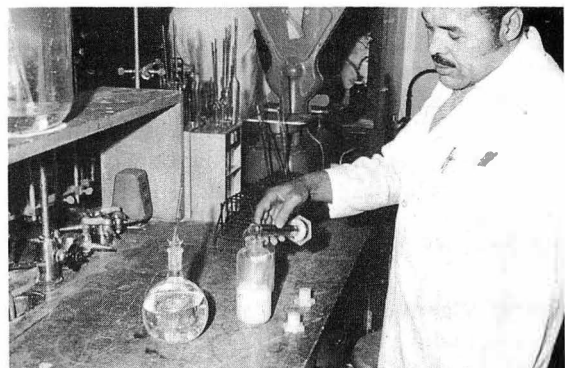
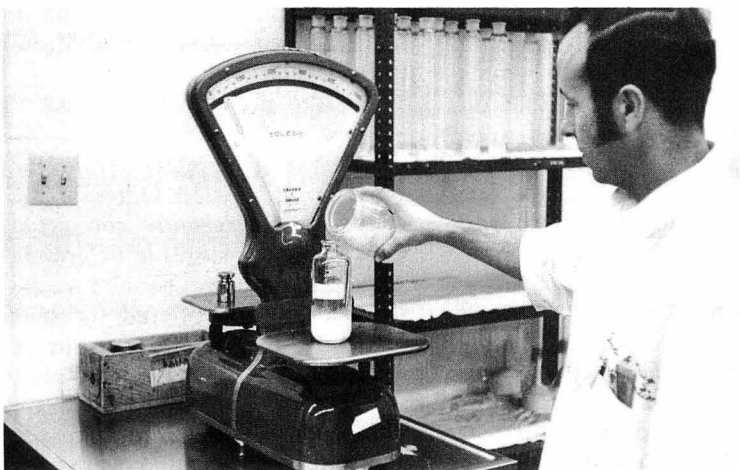
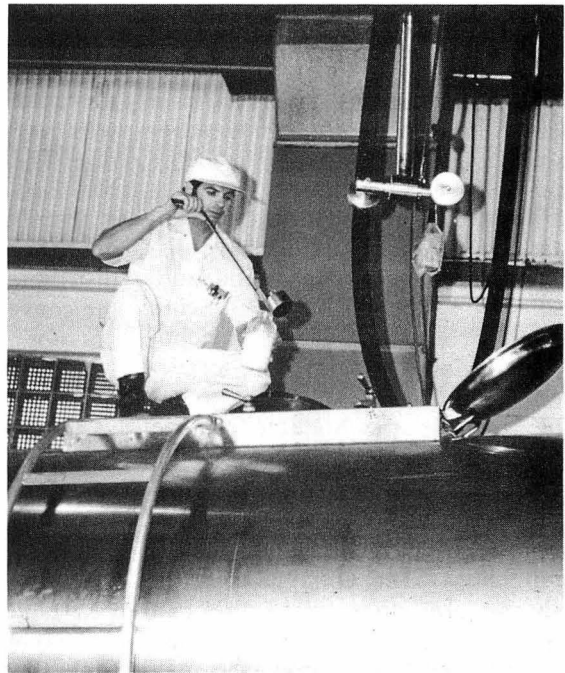
Pesticide residues in milk stem from a variety of sources . . . Cows grazing on pasture that has recently been sprayed with an herbicide or insecticide may cause contaminated milk . . .

Concentrated dairy feed stored and shipped in reused, treated grain seed bags has been the source of pesticide contamination of milk . . .

Hay brought from distant sources may be contaminated with pesticides, which will cause pesticide contamination of milk when fed to dairy cattle.

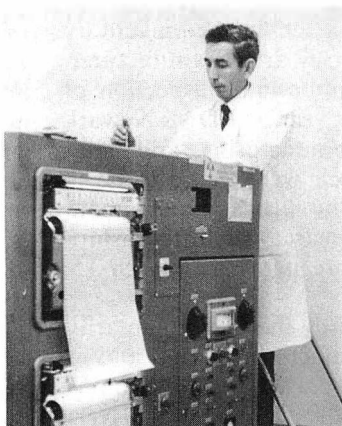


Don May, milk sanitarian from the Dallas City Health Department, samples a load of raw milk from Hopkins County, Texas.



Lab Technician James Miller extracts milk fat for pesticide analysis.

District Chemist Frank Hons weighs a milk sample in centrifuge bottle in preparation for pesticide determination.



Chemist Juan Tijerina injects a final sample extract into a gas chromatograph.



Robert E. Adams, regional milk consultant, Special Programs Branch, FDA Region VI, Dallas, entered active duty with the Public Health Service in 1963.

state actions

Seizure and Recall Inspectors from the Food Section of the Virginia Department of Agriculture and Commerce recently seized 3 million pounds of peanuts involved in a fire at a Richmond peanut warehouse. Disposition also is being handled by the inspectors.

The department's Hazardous Substances Section inspectors have discovered a "personality indicator" called "Mystery Bubbler Score Game" containing methyl alcohol in a Virginia toy store. The inspectors conducted a survey of other toy stores in the State to remove the device from sale, and the department requested that the distributor recall the product.

Ban Lifted The Ohio Division of Natural Resources lifted the ban on commercial fishing in Lake Erie. Fish between 9 and 10½ inches may now be legally taken. The ban remains in effect for walleye pike. The bans were instituted because of high mercury content in fish taken from Lake Erie. FDA's Cincinnati District will maintain surveillance over commercial shipments of fish when the lake is opened to fishing after the spring thaw.

'Scrap' Candy Earl Holstein, an inspector with the Missouri Division of Health, was concerned about a commercial on TV Station KYTV, Springfield, Missouri, advertising candy for six cents a pound at a local market, and indicating that although the candy was made by a nationally known manufacturer, the market was prohibited from using the name.

Mr. Holstein, who lives at Springfield, visited the market the next day and found the candy displayed in "lard" cans of varying size. The candy was melted and showed evidence of filth contamination and was undoubtedly "scrap." It was unlabeled, but a sign over the display identified the candy as a product of a Kansas City candy firm.

Enlisting the aid of the Springfield City Health Department, Mr. Holstein embargoed the lot of candy and took further steps to determine the actual source of the candy as well as further planned distribution. The source was determined to be a Fort Worth, Texas, firm through a distributor operating at Coffeyville, Kansas. When contacted, the distributor stated at one time in the conversation that the candy was not for human consumption but would not tell the purpose for which it was sold.

A total of 9,220 pounds of candy has been destroyed under official supervision and still under embargo is approximately 7,500 pounds. The involved distributors or jobbers or both exonerated the Kansas City candy manufacturer.

State/Federal Seminar The Laboratory Division of the Michigan Department of Agriculture and FDA's Region V Special Programs Branch co-sponsored a seminar on direct microscopic somatic cell count at Lansing, Michigan. Subject matter included microscope calibration, cell identification, and statistical evaluations.

Drugs Destroyed The New Jersey State Department of Health recently supervised the destruction of an estimated 45 tons of embargoed human dosage form drugs estimated by the State at approximately \$1,400,000 in value. The lot originally was part of the finished inventory of a New Jersey drug manufacturer. During an intensified inspection of that firm last year by FDA's Newark District, manufacturing and analytical controls were found to be so poor that the firm's management voluntarily ceased all further shipments of drug items on March 15, 1971.

Subsequently the firm voluntarily ceased manufacturing drugs, and in June 1971 ceased all operations and eventually went into receiver-

ship. FDA charged that 11 lots of drugs (ascorbic acid tablets, USP) worth approximately \$50,000 were prepared, packed, and held under insanitary conditions and they were seized. Approximately 115 additional lots of drugs were voluntarily destroyed nationwide or returned to the manufacturer to avoid seizure on similar charges. In addition, the firm voluntarily initiated 12 recalls of violative drugs. In October the court-appointed receiver sought to convert all the firm's assets, including its inventory of finished drugs, into cash, whereupon an FDA Newark District inspector—acting under the authority of his New Jersey State commission as a special agent—placed the entire drug inventory under State embargo.

The receiver said in January 1972 that he had no further interest in the lot and that as far as he was concerned, the lot was abandoned. State Department of Health authorities then ordered the lot destroyed and the embargo lifted.

Toy Survey Volunteers from the Consumer Protection Office of the city of Seattle recently completed a survey of area stores to determine whether specific toys banned by the FDA were being offered for sale. The study was limited to squeeze toys with "squeakers," which FDA has banned because the squeaker mechanism can be removed easily by infants. The team covered almost all major shopping areas of the city, and found a total of 167 banned toys on display in 13 separate stores. The investigation did not cover the stores' inventories, where more banned toys may be held pending display.

Besides noting the banned toys for sale, the team found other squeeze toys that appeared to incorporate the same explicit dangers as the banned toys. Some of the label information from these toys has been recorded by the Consumer Protection Office.

seizures & postal service cases

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

A total of 41 actions to remove from the consumer market products charged to be violative were reported in January/February. These included 26 seizures of foods: 1 involved charges concerning poisonous and deleterious substances, 21 involved charges concerning contamination, and 4 involved charges concerning economic and labeling violations. Other seizures included 4 of vitamins and dietary food, 8 of drugs (including 5 of veterinary and medicated feed), and 3 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Poisonous and Deleterious Substances		
Bulk feathermeal/Memphis, Tenn. 1/7/72	Standard Rendering Co./Russellville, Ark. (M,S)	Contains Salmonella micro-organisms.
Contamination, Spoilage, Insanitary Handling		
Flour/W. Monroe, La. 1/11/72	Simonton Grain Co./W. Monroe, La. (D)	Held under insanitary conditions; rodent contaminated.
Fruit cocktail/New Orleans, La. 1/19/72	F. G. Wool Packing Co., Inc./San Jose, Calif. (P)	Prepared and packed under insanitary conditions; contains machinery mold.
Montgomery, Ala. 1/28/72	"	"
Mama's wafer stix, Mama's sugar wafers/ Tulsa, Okla. 1/13/72	American Wafer Co./Joplin, Mo. (M,S)	Prepared and packed under insanitary conditions; rodent hairs.
Manley's Hi Pop popcorn/Minneapolis, Minn. 1/5/72	Shipped from Tarkio, Mo.	Insect contaminated, insect larvae, and larval cast skins.
Mushroom chips, canned/Kansas City, Kans. 2/4/72	Shipped from Warren, Mich.	Wholly or in part decomposed.
Olives/Atlanta, Ga. 1/12/72	Southgate Foods, Inc./Norfolk, Va. (M,S)	" ; moldy.
Peanuts, Spanish, shelled/Denver, Colo. 2/4/72	Denison Peanut Co./Denison, Tex.(S)	Held under insanitary conditions.
Pecans/Dallas, Tex. 2/9/72	Central Pecan Shelling Co./Mansura, La. (P,S)	Prepared and packed under insanitary conditions; E. coli.
Memphis, Tenn. 1/13/72	"	"
Memphis, Tenn. 1/18/72	"	E. coli.
Mansura, La. 1/11/72	Keathley's Baking Co./Memphis, Tenn. (S)	"
Rahway, N.J. 1/28/72	Montgomery Pecan Co., Inc./Montgomery, Ala. (P,S)	Partly decomposed and moldy.
Potatoes, dehydrated/Forest Park, Ga. 1/24/72	Idaho Fresh Pak, Inc./Lewistown, Idaho (M,S)	Insect contaminated.
Idaho Supreme, au gratin, dried, Idaho Supreme, scalloped, dried/ Nashville, Tenn. 1/25/72	Central-Cumberland Corp./Nashville, Tenn. (D)	"
Sather's checker wafer, wafer stix/ Round Lake, Minn. 1/13/72	American Wafer Co./Joplin, Mo. (M,S)	Prepared and packed under insanitary conditions; rodent con- taminated.
Creme Delite cookies/Round Lake, Minn. 1/13/72	"	Prepared, packed, and held under insanitary conditions; rodent contaminated.
SBS brand California cranberry beans/ Fresno, Calif. 2/3/72	Marbo Quality Foods, Inc./Fresno, Calif. (D)	Held under insanitary conditions; rodent contaminated.
Soups, various, canned/Bronx, N.Y. 1/20/72	Bon Vivant Soups, Inc./Newark, N.J. (M,S)	Prepared under insanitary conditions; defective and abnormal cans.
Bronx, N.Y. 1/19/72	"	"
Great Neck, N.Y., Plandome, N.Y., Atlantic Beach, N.Y., Glen Cove, N.Y., Merrick, N.Y., and Brooklyn, N.Y. 1/24/72	"	"

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Economic and Labeling Violations		
Oysters, canned, smoked/Denver, Colo. 1/25/72	Imported from Japan. Bien Trading Co., Inc., thru Hanover Ter., Inc. Penn TWP/Hanover, Pa. (S)	Not in conformity with the Fair Packaging and Labeling Act.
Pecan halves/Charleston, S.C. 2/3/72	H. M. Thames Pecan Co., Inc./Mobile, Ala. (M,S)	"
Soyagen (carob, malt flavors, liquid), Soyalac (ready-to-serve)/Denver, Colo. 1/25/72	Loma Linda Foods Co./Mount Vernon, Ohio, and Riverside, Calif. (M,S)	"
Tomatoes, canned/Kansas City, Kans. 2/1/72	Sun Garden Packing Co./San Jose, Calif. (P,S)	Below quality standard for canned tomatoes; too much peel.

Vitamins—Dietary Food

Aceroflavon tablets, Rutin tablets, Naturolavons tablets, Bioflavonoid-C tablets, Super Bio-C tablets, Super Naturolavons tablets, Chewable Vitamin C tablets with Acerola, C-Rutin tablets/ Pittsburgh, Pa. 1/31/72	General Nutrition Corp./Pittsburgh, Pa. (D)	False and misleading claims for nutritive value of hesperidin and/or rutin and/or citrus bioflavonoids singly or in com- bination with vitamin C; false and misleading claims for necessity and usefulness of 250 mg., 600 mg., or 300- 600 mg. of vitamin C per day.
Hy-C tablets/Dallas, Tex. 2/3/72	Solgar Co., Inc./New York, N.Y. (M,S)	False and misleading claims of special dietary properties as a supplement and to be of therapeutic use.
New Diet Sweet***Low Calorie imitation maple flavor Maplette/Minneapolis, Minn. 1/12/72	Duffy-Mott Co., Inc./Santa Clara, Calif. (M,S)	False and misleading labeling representing article as artificially sweetened, whereas it is sweetened in part with sugar; "Flav-O-Lock" is not the common and usual name of an ingredient.
Vitamin-Mineral tablets Rx 1726R control 17010 and 17870, and number 518/Cedar Rapids, Iowa 1/31/72	Private Formulae, Inc./St. Louis, Mo. (M,S)	False and misleading claims to be of specific dietary value.

DRUGS / Human Use

King's Con-Tin clinical mouth rinse concentrate/Houston, Tex. 1/7/72	King's Specialty Co., Inc./Fort Wayne, Ind. (M,S)	Not in conformity with good manufacturing practice.
Ophthalmic ointment/Iowa City, Iowa 1/24/72	Muro Pharmacal Labs., Inc./Quincy, Mass. (M,S)	Below purported quality.
Sodium fluoride paste/Fort Wayne, Ind. 1/18/72	King's Specialty Co., Inc./Fort Wayne, Ind. (M,D), shipped from St. Louis, Mo.	Not in conformity with good manufacturing practice.

Veterinary / Medicated Feed

Coop Liquid Concentrate-100/Greenleaf, Kans. 2/11/72	Farmland Industries, Inc./Fremont, Nebr. (M,S)	New animal drug without effective approved New Animal Drug Application; contains diethylstilbestrol.
Kent Super A-D Primer (medicated feed)/ Sioux City, Iowa 2/7/72	Kent Feeds, Inc./Sioux City, Iowa (M,D); Raw Material: American Cyanamid/ Rosemont, Ill. (S)	" ; not in conformity with good manufacturing practice.
Liquid Animal Feed/Rock Port, Mo. 2/3/72	Allied Chemical Corp./Omaha, Nebr. (M,S)	New animal drug without effective approved New Animal Drug Application; contains diethylstilbestrol.
Liquid Feed Concentrate/Aberdeen, S. Dak. 1/31/72	Hub City Feed & Seed, Inc./Aberdeen, S. Dak. (D)	"
Nonmedicated liquid animal feed "Compensator PR Liquid Feed Supplement"/ Stamford, Nebr. 1/13/72	Allied Chemical Corp./Omaha, Nebr. (M,S)	"

HAZARDOUS SUBSTANCES

Concern liquid laundry product/Olean, N.Y. 2/8/72	H. T. Developments, Inc./Buffalo, N.Y. (M)	Lacks consumer protection information required by the Fed. Hazardous Substances Act; toxic and irritant.
Super Concentrate Concern/Buffalo, N.Y. 1/27/72	"	"
Toy clown doll/New Orleans, La. 1/19/72	Imported. M. Pressner & Co., Inc./New York, N.Y. (S)	Banned hazardous substance; flammable.

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 Assistant Postmaster General—Inspection Service.

No information available for this issue.

notices of judgment

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

Bonita fish, at New Bedford, Dist. Mass.

Charged 5-17-71: when shipped by Woodfield Fish & Oyster Co., Galesville, Md., the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Consent decree ordered destruction. (1)

Feathermeal, at Jackson, S. Dist. Miss.

Charged 3-17-71: when returned to Griffin Industries, Jackson, Miss., from Palestine, Tex., the article contained the added poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). Consent decree authorized release to shipper for reconditioning. (2)

Swordfish chunks, frozen, at San Diego, S. Dist. Calif.

Charged 4-12-71: when shipped from waters outside the territorial limits of California, the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (3)

Swordfish fillets, frozen, at Seattle, W. Dist. Wash.

Charged 2-22-71: when shipped by Chas. P. Kearney & Co., Oakland, Calif., and Nozaki Association, San Francisco, Calif., the article, labeled in part "Geisha San Francisco Frozen Swordfish Fillet . . . Product of Japan," contained the added poisonous and deleterious substance mercury; 402(a)(1). Consent decree authorized release to Nozaki Associates, Inc., New York, N.Y., for export to original foreign shipper. (4)

Swordfish steaks, frozen, at Albany, N. Dist. N.Y.

Charged 3-1-71: when shipped by Slade Gorton & Co., Inc., Boston, Mass., the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Consent decree ordered destruction. (5)

Swordfish, whole, frozen, at Panama City, N. Dist. Fla.

Charged on or about 3-9-71: when returned from New York, N.Y., to Cook Fish Co., Panama City, Fla., the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (6)

FOOD / Contamination, Spoilage, Insanitary Handling

Cocoa beans, at Camden, Dist. N.J.

Charged 7-26-71: while held for sale, the article contained moldy cocoa beans; 402(a)(3). Default decree ordered destruction. (7)

Cookies, at Miami, S. Dist. Fla.

Charged 3-2-71: while held for sale, the article was unfit for food because of rancid cookies—402(a)(3); and required information concerning the name and place of business of the manufacturer, packer, or distributor, the quantity of contents, and the common or usual name of the food and its ingredients was not in terms likely to be read and understood by the ordinary individual, since it was stated in Spanish and not in English—403(f). Consent decree ordered destruction. (8)

Flour, at Liberal, Dist. Kans.

Charged 4-8-71: while held by Ideal Food Stores, Inc., Liberal, Kans., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (9)

Onion rings, breaded, frozen, Chef's, at Dallas, N. Dist. Tex.

Charged on or about 1-19-71: when shipped by Gus's Frozen Onion Rings, Okmulgee, Okla., the article contained bacterial filth; the article had been prepared and packed under insanitary conditions; and the article's label lacked the name and place of business of the manufacturer, packer, or distributor; 402(a)(3), 402(a)(4), 403(e)(1). Default decree ordered destruction. (10)

Peanuts, shelled, at Beaverton, Dist. Ore.

Charged 4-2-71: while held for sale, the article contained rodent filth; 402(a)(3). Consent decree ordered destruction. (11)

Peas, Alaska, and beans, pink, at Santurce, Dist. P.R.

Charged 5-12-71: while held by Caribe Warehouse Corp., Santurce, P.R., the articles contained rodent filth and were held under insanitary conditions—402(a)(3), 402(a)(4); and when shipped by Sinsheimer & Co., San Francisco, Calif., the label of the peas lacked the name and place of business of the manufacturer, packer, or distributor, and lacked a statement of quantity of contents—403(e)(1), 403(e)(2). Consent decree authorized release to F. Badrena e Hijo, Inc., San Juan, P.R., for reconditioning. (12)

Pecan pieces, at New York, S. Dist. N.Y.

Charged 3-25-71: when shipped by Nut Tree Pecan Co., Albany, Ga., the

article contained *E. coli* and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the shipper for reconditioning. (13)

Pistachio nuts, at Terra Bella, E. Dist. Calif.

Charged 6-25-71: while held by Kerman Pistachio of California, Terra Bella, Calif., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for reconditioning. (14)

Rice, coffee-chicory mixture, and cake mix, at Selma, S. Dist. Ala.

Charged 3-5-71: while held by Steward King & McKenzie Wholesale Grocery Co., Selma, Ala., the articles were held under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (15)

Soup, turtle, canned, at Cincinnati, S. Dist. Ohio.

Charged 9-15-71: when shipped, the article, labeled in part "Sexton Clear Green Turtle Soup with Sherry Wine . . . Distributed by John Sexton & Company Div. of Beatrice Foods Co., Chicago, Ill.," was unfit for food in that some cans of this food 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 article had been prepared, packed, and held [by Bon Vivant Soups, Inc., Newark, N.J.] under conditions whereby they may have been rendered injurious to health; 402(a)(3), 402(a)(4). Default decree ordered destruction. (16)

Soups of various kinds, canned, Bon Vivant and Ancora, at San Francisco, N. Dist. Calif.

Charged 8-16-71: when shipped by Bon Vivant Soups, Inc., Newark, N.J., the articles were unfit for food in that some cans were 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 conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health; 402(a)(3), 402(a)(4). Default decree ordered destruction. (17)

Walnut pieces, Blue Ribbon Planters Special, at Suffolk, E. Dist. Va.

Charged 5-7-71: when shipped by Continental Nut Co., Chico, Calif., the article contained insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the shipper for reconditioning. (18)

Whiting, frozen, at Gloucester and Boston, Dist. Mass.

Charged 12-1-70: when shipped by J. C. Murray, Brooklyn, N.Y., the articles, labeled in part "Sea 'n' Stream Brand Net Wt. 5 Lbs. . . . Dressed Whiting [or "Net Wt. 66 Lbs. . . . Frozen Whiting Blocks"] . . . Packed for King Imports Co., San Mateo, Calif. . . . Product of Argentina," contained decomposed fish; 402(a)(3). Default decree, as to the dressed whiting seized at Gloucester, ordered destruction. Consent decree, as to the frozen whiting blocks at Boston, authorized release to King Imports Co., San Mateo, Calif., for export to West Germany for use as pet food. (19)

FOOD / Economic and Labeling Violations

Beverage, carbonated, dietetic, Dr. Pepper, at Mobile, S. Dist. Ala.

Charged on or about 12-4-70: while held by Pepsi Cola Dr. Pepper Bottling Co., Mobile, Ala., who manufactured the article without cyclamates from invert sugar and certain other ingredients shipped in interstate commerce, the article's carton label and bottle labels contained the false and misleading statements "Low Calorie . . . Sugar Free," "Artificially sweetened," "Low Calorie Sugar Free," "Sodium cyclamate," "Contains 0.088% sodium cyclamate," "0.21% [and "0.28%] available carbohydrates," and "¼ [and "½"] calorie per fl. oz."—403(a); and the article lacked the common or usual name of each ingredient, since "invert sugar" was not declared—403(i)(2). Consent decree authorized release of the article to the manufacturer for destruction of the contents of the bottles, the bottle caps, and cartons, and for salvaging the bottles and crates. (20)

Beverage mix, chocolate-flavored, Yoo-Hoo, at Atlanta, N. Dist. Ga.

Charged 7-30-71: when shipped by Yoo-Hoo Beverage Co., Carlstadt, N.J., the article was short weight; 403(e)(2). Default decree authorized donation to charitable institution. (21)

Candies, lime sticks, and raspberry fills, at Mableton, N. Dist. Ga.

Charged 11-30-70: when shipped by Lamme's Candies Since 1885, Inc., Austin, Tex., the articles were in violation of the Fair Packaging and Labeling Act, since the articles' labels lacked the name and place of business

of the manufacturer, packer, or distributor; the quantity of contents declaration was not placed within the bottom 30 percent of the area of the principal display panels; the quantity of contents statements were not expressed as required, since the terms "Net Weight" or "Net Wt." were not used; and the quantity of contents, on the principal display panels with areas more than 5 square inches, were in type size less than 1/8 inch high—15 U.S.C. 1453(a)(1), 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i); and the quantity of contents statement of the raspberry fill candy was expressed as "1 1/2 Lb." instead of "Net Wt. 24 Oz. (1 1/2 Lb.)"—15 U.S.C. 1453(a)(3)(A)(i). Default decree authorized donation to charitable institution. (22)

Peppers, pickled, at Philadelphia, E. Dist. Pa.

Charged 11-20-70: when shipped by Perfect Packed Products, Henderson, N.C., the article, labeled in part "Fresh Pack Colonial Perfect Packed Products Co., Inc. . . . Pimientos Halves . . . Ingredients: Pimientos, Salt and Vinegar," was red bell peppers offered for sale under the name of another food, and the article's label lacked the name of each ingredient; 403(b), 403(i)(2). Default decree authorized donation to charitable/public institution. (23)

Pineapple tidbits, canned, at Jacksonville, M. Dist. Fla.

Charged 12-3-70: when shipped by Taiwan Kagome Co., Ltd., Taiwan, China, the article, labeled in part "Liberty Brand . . . Pineapple Pieces in Heavy Syrup . . . Packed for Setico Import Co. Jacksonville, Florida," failed to bear the correct name of the optional pineapple ingredient, namely, "Tidbits," as prescribed by the definition and standard of identity for canned pineapple—403(g)(2); and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not separated from other printed label information appearing below the declaration—15 U.S.C. 1453(a)(2). Consent decree authorized release to National Merchandise Co., Inc., Jacksonville, Fla., for relabeling. (24)

Sour cream, pasteurized, processed, Borden's, at Little Rock, Dist. Ark.

Charged 7-23-71 and amended 7-26-71: when shipped by Mid-America Dairymen, Inc., Little Rock, Ark., on behalf of Borden's, Inc., Houston, Tex., the article consisted of a number of substances, including tapioca starch, locust gum, guar gum, rennet, and culture aroma, which had been substituted for sour cream—402(b)(2); culture aroma had been added to and packed with the article so as to make it appear better than it was—402(b)(4); the article was a multi-ingredient, processed, hot-pack, cream product which was, in part, nonbacteriologically acidified, and the article was offered for sale under the name of another food, namely "Sour Cream"—403(b); the name and place of business of the distributor and the name of each ingredient were not prominently placed on the label with the required conspicuousness, since such information appeared in a circle of blurred type in the margin of the lid of the article and such information was crowded with other printed matter including both printed and embossed patent numbers—403(f). Mid-America Dairymen, Inc., Little Rock, Ark., claimed the article and denied the charges. The claimant served written interrogatories on the Government. Thereafter the parties agreed that the article had decomposed since its seizure, which meant that the article was adulterated within the meaning of 402(a)(3). Therefore, without prejudice or any admissions concerning the charges of the complaint, a consent decree condemned the article and ordered its destruction. (25)

FOOD ADDITIVES

Earthenware plates and bowls, at New York, S. Dist. N.Y.

Charged 8-20-70: when shipped by Aurora Palos, Jalisco, Mexico, Alfareria Aldana, Jalisco, Mexico, and Ceramica De Daxaca, Oaxaca, Mexico, the articles contained the nonconforming food additive lead, which acid solutions would leach out; 402(a)(2)(C). Consent decree authorized release to Fred Leighton Imports, Ltd., New York, N.Y., for compliance operation rendering the articles unfit for use as containers for food and drink by drilling holes in the articles. (26)

Feta cheese, at Methuen, Dist. Mass.

Charged 2-23-71: when shipped by Moscahlades Bros., Inc., New York, N.Y., the article contained the nonconforming food additive benzene hexachloride; 402(a)(2)(C). Default decree ordered destruction. (27)

VITAMINS / SPECIAL DIETARY FOODS

Geri-Vim dietary supplement tablets, at Pawtucket, Dist. R.I.

Charged 7-15-71: while held for sale after being partially repacked by Adams Drug Co., Inc., Pawtucket, R.I., the article had had the valuable constituents calcium pantothenate and vitamin B₁₂ partially omitted or abstracted; and the ingredient statements as to those constituents were false and misleading, since the article contained less than 34 percent of the declared calcium pantothenate and less than 50 percent of the declared vitamin B₁₂—402(b)(1), 403(a); the label statement of the repacked tablets "Need in human nutrition not established" was false and misleading, since it was contrary to fact—403(a); and the label statement of the repacked tablets "Each tablet Contains: . . . Methionine 25 mg." was false and misleading in representing that the article was of special dietary value by reason of such ingredient—403(a). Default decree ordered destruction. (28)

DRUGS / Human Use

Estrand-Gens methyltestosterone tablets, at Valley Stream, E. Dist. N.Y.

Charged 4-26-71: when shipped by Richlyn Laboratories, Inc., Philadelphia, Pa., the article's strength differed from its purported strength, since it con-

tained approximately 80 percent of the declared amount of methyltestosterone; 501(c). Default decree ordered destruction. (29)

Hyoscyamine sulfate combination tablets, at Tucker, N. Dist. Ga.

Charged 12-18-70: while held for sale, the strength of the article differed from its purported strength, since the article contained approximately 45 percent of the declared amount of hyoscyamine sulfate; 501(c). Default decree ordered destruction. (30)

Rauwolfia serpentina tablets, N.F., at Melville, E. Dist. N.Y.

Charged 4-26-71: when shipped by Richlyn Laboratories, Inc., Philadelphia, Pa., the article's strength differed from the N.F. standard, since the reserpine-rescinnamine group alkaloids was approximately 80 percent of the N.F. minimum; 501(b). Default decree ordered destruction. (31)

Sedatans sedative tablets and Hy-Po-Tone tonic tablets, at Philadelphia, E. Dist. Pa.

Charged 4-1-71: while held by High Chemical Co., Philadelphia, Pa., who manufactured the articles from ingredients shipped in interstate commerce, the articles had been manufactured, processed, packed, and held under circumstances that lacked conformity with current good manufacturing practice; and the articles failed to bear adequate directions for use and were not exempted therefrom, since they lacked adequate information for use by licensed practitioners for their intended purposes; 501(a)(2)(B), 502(f)(1). Default decree ordered destruction. (32)

Thyroid tablets, U.S.P., at Plainview, E. Dist. N.Y.

Charged 12-17-70: when shipped by Marshall Pharmacal Corp., South Hackensack, N.J., the article contained mold; 501(a). Default decree ordered destruction. (33)

DRUGS / Veterinary

Afaco calcarea fluoria combination tablets, at Miami, S. Dist. Fla.

Charged 8-14-70: when shipped by Farnsworth Laboratories, Inc., Chicago Heights, Ill., and by International Afaco Ltd., Columbus, Ga., and while held by Bayshore Veterinary Clinic, Miami, Fla., the article (some of which had been repacked by the dealer) was a new animal drug without an effective approved New Animal Drug Application; the reprints entitled "Afaco" accompanying the article contained false and misleading claims for cataracts in dogs; and the article's labeling lacked adequate directions for use for its intended purposes; 501(a)(5), 502(a), 502(f)(1). The article was claimed by E. H. Majilton, D.V.M. Subsequently he filed an answer and denied the charges. The Government served written interrogatories on the claimant. Thereafter, the claimant withdrew his answer and a default decree ordering destruction of the article was entered. (34)

Ferro-Lac Calf and Cattle Formula medicated concentrate, at Norfolk, Dist. Nebr.

Charged 5-23-66 and amended on or about 3-30-67: when shipped by Naremcro, Inc., Springfield, Mo., the article contained the nonconforming food additives methylrosaniline chloride, sodium phthalylsulfacetamide, and sodium propionate; the article's labeling contained false and misleading claims for control and treatment of infectious enteritis in calves and cattle; and the article was a new drug without an effective approved New Drug Application; 402(a)(2)(C), 502(a), 505(a). The article was claimed by the shipper who denied the charges. The parties served interrogatories upon each other. After answers to the interrogatories were received, the Government moved for summary judgment upon the charges that the article was a new drug without an effective New Drug Application and that the article was a nonconforming food additive.

In finding for the Government, the court said:

"Interrogatory #12 propounded to claimant by the Libelant requests in part: the names of each person whom the claimant knows to be of the opinion that Ferro Lac is adequate and effective for the prescribed purposes, and citations to all scientific literature which supports such conclusions. Claimant responded to said interrogatory with the names of 24 doctors from 11 States and a wealth of citations of medical articles. This writer has carefully reviewed the citations submitted; and as previously noted not one addresses itself to an evaluation of the combinations of drugs contained in Ferro Lac, but instead are either general veterinary articles or a consideration of the individual chemicals contained in Ferro Lac.

"Accordingly, construing Dr. Whittaker's affidavit [submitted by claimant] and claimant's response to Libelant's interrogatories in favor of claimant, this Court still finds nothing more than a personal opinion and unsupported conclusions to support the contention of general recognition of Ferro Lac with the statutory definition. In opposition to claimant's contention, the Government has submitted an affidavit which states factually that there is not general recognition of the Ferro Lac or of any compound with similar ingredients generally recognized as safe and effective for the purpose for which the drug is sold and recommended.

"This Court thus concludes that on the 'new drug' issue there is no genuine issue as to a material fact.

"In response to Libelant's interrogatory #22, the claimant admits that use of Ferro Lac results in it becoming a part of the food for calves and cattle. Accordingly, the product must be considered a food within 21 U.S.C. § 321(f). * * *

"Section 348 of Title 21 provides that a food additive shall be deemed to be unsafe unless its use or intended use conforms to the terms of an exemption in effect or its use or intended use are in conformity with regu-

lations in effect and issued under the section prescribing the conditions under which such additives may be safely used. 21 U.S.C. § 348(a)(1) and (2). No exemption or regulation in regard to the above exists with reference to Ferro Lac. Thus this issue is whether Ferro Lac is a food additive and the product cannot escape that label unless it meets the . . . ["generally recognized as shown through scientific procedures to be safe"] provisions of 21 U.S.C. § 321(s). * * *

"However, the affidavit [submitted by claimant] contains no reference to writings or periodicals or journals that would substantiate that Ferro Lac has been shown 'through scientific procedures' to be safe.

"The affidavit does not address itself by objective proof to the critical test of general recognition in the scientific community that Ferro Lac has been shown through scientific procedures to be safe, and instead contains but an inference, based on an analysis of its individual ingredients, that the compound might be shown to be safe.

"The affidavit submitted on behalf of the Government substantiates the fact that there is a lack of general recognition among experts qualified by scientific training and experience to evaluate its safety of Ferro Lac as having been 'adequately shown through scientific procedures to be safe under the conditions of its intended use.' 21 U.S.C. § 321(s).

"Thus in regard to the claim of the Government that Ferro Lac is an adulterated food there is no genuine issue as to any material fact.

"Accordingly, as there is no genuine issue as to any material fact in regard to the 'new drug' and adulterated food claims, the Government is entitled to summary judgment and the relief prayed for." (35)

Leamycin oxytetracycline hydrochloride injectable, at Newman Grove, Dist. Nebr. Charged 6-16-71: while held for sale [after manufacture by Wartig Veterinary Clinic, Wisner, Nebr., from oxytetracycline hydrochloride powder shipped in interstate commerce], the article was a new animal drug without an effective approved New Animal Drug Application; 501(a)(5). Default decree ordered destruction. (36)

Dr. Mayfield Oxy-Tet oxytetracycline hydrochloride injectable, at Norfolk, Dist. Nebr. Charged 3-24-71 and amended 4-22-71: when shipped by Dr. Mayfield Laboratories, Inc., Charles City, Iowa, the article was a new animal drug without an effective approved New Animal Drug Application; 501(a)(5). Default decree ordered destruction. (37)

Natamycin oxytetracycline hydrochloride injectable, at Belle Plaine, Dist. Minn. Charged 5-20-71: while held by Wendt Laboratories, Inc., t/a Professional Veterinary Laboratories, Inc., Belle Plaine, Minn., who manufactured the article from oxytetracycline hydrochloride shipped in interstate commerce, the article was a new animal drug without an effective approved New Animal Drug Application; 501(a)(5). Default decree ordered destruction. (38)

MEDICAL DEVICES

Relaxacizor electric muscle stimulator, at Seattle, W. Dist. Wash. Charged 8-19-70: when returned to purchaser who had shipped the article for repair to Relaxacizor, Inc., Los Angeles, Calif., the article's labeling lacked adequate directions for safe use by a layman and lacked adequate warnings against unsafe use; 502(f)(1), 502(f)(2). The article was claimed by Janet M. Miller, Seattle, Wash. A consent decree of condemnation was entered condemning the device and providing that the parties might submit memoranda and supporting affidavits regarding the proper disposition of the device. In ordering that the article be disposed of by destruction, the court said:

"Under 21 U.S.C. § 334(d), the Court has several alternative methods for disposal of the condemned device. Depending on the circumstances of each case, a court may order the sale or destruction of a misbranded device by the government, or its return to the owner for relabeling, alteration, destruction or re-exportation. The claimant asks that the Court order the device returned for her personal use until, by ordinary wear and tear, its life comes to a close. Before the Court can enter such an order, however, it must be satisfied that the device could be 'brought into compliance with the provisions of' 21 U.S.C. § 352 (f).

"The Court finds that a label bearing adequate directions for use; and . . . adequate warning against use . . . where its use may be dangerous to health, or against unsafe . . . methods or duration of administration or application . . . [21 U.S.C. § 334(d)] cannot and should not be devised in these circumstances. The Court is sympathetic to the position of claimant, and understands her irritation at the government's actions. However, the device is inherently a very dangerous product, and there is no method by which its use may be rendered safe. In such circumstances the Court cannot, and will not, take the responsibility of returning it to her." (39)

Relaxacizor electric muscle stimulators, three seizure actions at San Francisco, N. Dist. Calif., Tucson, Dist. Ariz., and Santa Barbara and Redondo Beach, C. Dist. Calif. Charged 8-18-70, 8-21-70, and 9-9-70: when shipped, the labeling of the articles lacked adequate directions for safe use by laymen, and lacked adequate warnings against unsafe use; 502(f)(1), 502(f)(2). Default decrees ordered destruction. (40)

Respirator, Res-Q-Aire, at Webster, W. Dist. N.Y. Charged 9-8-69: when shipped by Res-Q-Aire, Inc., Canton, Ohio, the article bore the name Res-Q-Aire and statements on the carton label and attached card which were false and misleading as to the adequacy and

effectiveness of the article as a means of resuscitation; the labeling lacked adequate directions for use, and such could not be written, since the article was neither safe nor effective for its intended purposes; the labeling lacked adequate warnings against use involving obstructions, aspirated objects and dentures, and involving infants or children where the volume of air would be excessive; and the article was dangerous to health when used as prescribed; 502(a), 502(f)(1), 502(f)(2), 502(j). Consent decree ordered destruction. (41)

Sizatometer vacuum pump, at Las Vegas, Dist. Nev.

Charged 4-27-71: when shipped by Osiris, San Francisco, Calif., the article's labeling contained false and misleading claims for increasing the size of the user's penis; the article lacked adequate directions for use for such purpose, and such directions could not be written because the article was worthless for such purpose, the article lacked adequate warnings against unsafe use; and the article was dangerous to health when used as directed, since by the very nature of its use, existing medical conditions might be aggravated and since the article had the potential to contuse and rupture subcutaneous vessels; 502(a), 502(f)(1), 502(f)(2), 502(j). Default decree ordered destruction. (42)

Theramatic model A-60T40 electronic instrument, at Beaver Dam, E. Dist. Wis.

Charged 4-1-70: when shipped by Edison Park Laboratories, Elk Grove Village, Ill., the labeling of the article contained false and misleading claims for infections, otitis media, fractures, bone and tissue healing, smooth muscle spasm, including spasm of the colon; bursitis, arthritis, low back pain, headaches—parietal and occipital; urinary tract infections; ulcers, decubital; prostatitis; and sinusitis (allergic); its labeling lacked adequate directions for its intended uses, and such could not be written, since the article was worthless for such uses; and the article was dangerous to health when used as directed, since it was ineffective for treatment of serious disease conditions; 502(a), 502(f)(1), 502(j). The article was claimed by E. M. Keller, D. O., Beaver Dam, Wis., who denied the charges. The Government served interrogatories on the claimant. Thereafter, a consent decree of condemnation was entered. (43)

HAZARDOUS SUBSTANCES

Castor bean seed packages, at Fredonia, W. Dist. N.Y.

Charged 6-4-71: while held by Fredonia Seed Co., Fredonia, N.Y., who packaged the article from bulk castor beans from Haiti, the article was toxic and it lacked a number of required conspicuous label statements; 2(p)(1)(D,E & J). Default decree ordered destruction. (44)

Great Western alcohol, at Kansas City, W. Dist. Mo.

Charged 5-14-71: while held for sale after receipt in quart and gallon cans from Harker Paint & Varnish Co., Springfield, Mo., who had received bulk alcohol from Louisiana, the article was toxic and presented a special hazard because of its approximately 100 percent methyl alcohol content, and it lacked a number of required conspicuous label statements; 2(p)(1)(E), 3(b). Default decree ordered destruction. (45)

NOTICES OF JUDGMENT on Criminal Actions

FOOD

Daniel R. Crawley, t/a Wolf Flour Cartage Co., Chicago, N. Dist. Ill.

Charged 7-12-71: flour was held in a building accessible to rodents and was contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (46)

Leonard C. Landers, t/a Landers Wholesale Grocery Co., Vernon, N. Dist. Tex.

Charged 5-13-71: popcorn and two kinds of candy bars were held in a building accessible to insects and were contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (47)

Henry Lee Co., Henry Sternlieb, president, and **Sol M. Sternlieb**, vice president, Miami, S. Dist. Fla.

Charged 12-30-70 by grand jury: flour was held in a building accessible to rodents and was contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty pleas by individuals; fines, imprisonments suspended, and probations. Guilty plea by corporation; fine. (48)

DRUG

Bronx Drug Co., Inc., and Isaac Zonana, president, Bronx, S. Dist. N.Y.

Charged 6-12-70 in petition for order to show cause in criminal contempt: in violation of a consent decree of permanent injunction, Triavil tablets and blue and white placebo capsules were held and stored at Mount Vernon, N.Y., under circumstances lacking current good manufacturing practice; and Parafon tablets were held and stored at Bronx, N.Y., under circumstances lacking current good manufacturing practice; 501(a)(2)(B). The defendants denied the charges and alleged that the petition failed to state essential facts, that they had surrendered their State certificates for drug operations, and that the Government had proceeded against the same drugs in an in rem action, and therefore the Government should be estopped from a criminal contempt action. The defendants also moved to dismiss the proceedings on the grounds that (1) the proceeding was barred by a 1-year Statute of Limitations and (2) the moving papers failed to allege service of a certified copy of the consent decree. The defendants' motions to dismiss were denied; and, after trial by the court, the defendants were found guilty. In finding the defendants guilty of criminal contempt, the court said in part:

"Mr. Zonana testified that Bronx Drug had been in the business of repackaging drugs until the issuance of the Consent Decree. Thereafter, Bronx Drug's sole business was the buying and reselling of drugs and related merchandise. Newly purchased merchandise would be brought to the Mount Vernon building, where the resalable merchandise would be separated from the damaged merchandise. The resalable merchandise would then be brought to Watson Avenue, and the damaged merchandise would be left in Mount Vernon until it could be returned to the seller or destroyed.

"On January 11 and 12, 1968, the Mount Vernon and the Bronx premises were inspected by FDA inspectors to determine the conditions under which the defendants were storing drugs.

"In Mount Vernon on January 11, the FDA inspectors found a room behind the main storage room 8 feet by 12 feet in size, windowless, unlit, damp and cold. Inside this room the inspectors found two cardboard drums. One drum (Government exhibit 8) contained approximately 133,000 Triavil tablets manufactured by Merck in West Point, Pennsylvania between August and November of 1965. A representative of Merck testified that the tablets were rejects because of physical deformities such as cracks, chips or smudges. The label on the drum identified its contents as Thibenzole Bolus 2GM, a drug administered to animals, while Triavil is a drug used for psychotherapeutic purposes on human beings.

"The second drum (Government exhibit 7) contained approximately 125,000 capsules of the Placebo of the drug Indomethacin manufactured by Merck in West Point, Pennsylvania between May and December of 1964. Indomethacin is an anti-inflammatory drug used in the treatment of arthritis, and the Placebo was intended to be used solely in the clinical testing of the Indomethacin. No identifying label was on the drum.

"On January 12, 1968, the FDA inspectors inspected two basement storerooms at Watson Avenue and found them cold, damp and dirty. Over-the-counter drugs and prescription drugs were in cartons which were strewn about the rooms in a haphazard manner. In one storeroom, dust was observed on bottles of drugs.

"Following the inspection, a seizure order was issued by the FDA, and between 5 and 6 p.m. on January 12 the contents of the two storerooms were removed to the FDA district office in Brooklyn.

"Among the items seized was a bottle containing Parafon tablets (Government exhibit 31) which were manufactured by McNeil Laboratories in Philadelphia or West Point, Pennsylvania and which were not in their original bottle or in a bottle manufactured by McNeil Laboratories. Although McNeil Laboratories did not authorize repacking of its drugs, the label on the bottle stated that the tablets had been repacked by Isaac Zonana. The label did not carry a quantity statement, and tests run by an FDA analytical chemist revealed that the lot number on the label was not the same as the lot number of the tablets in the bottle.

"Mr. Zonana testified that the drugs in the Bronx storerooms had not been intended for resale. He stated that these drugs had been there since the issuance of the Consent Decree, which enjoined their sale, and that he intended to destroy them but had been too busy to do so. No sign or label was found to indicate that the drugs were intended to be destroyed.

"The issue in this proceeding is whether the methods and facilities used in the holding and storing of these drugs conformed with current good manufacturing practice as set out in the regulations promulgated under the Federal Food, Drug and Cosmetic Act.

* * * * *

"The Government's expert witness, Dean Joseph Kanig of the Columbia College of Pharmacy, testified that the manner in which the drugs were stored violated 'the sense and the letter of good manufacturing practices.' The court agrees.

"The drums containing the Triavil and the Placebo found at Mount Vernon were not labeled in conformity with good manufacturing practices as the labels did not correctly identify the contents of the drums or state the history of the manufacture and control of the drugs, 21 C.F.R. 133.10. The room in which the drugs were stored was cold, damp and poorly lit and therefore did not meet the standards of 21 C.F.R. 133.3. Moreover, as Dean Kanig pointed out, if the drugs were quarantined or ear-marked for destruction, current good manufacturing practice would have required that such information be placed on their containers.

"The manner in which the Parafon tablets were stored at Watson Avenue also violated current good manufacturing practice. The most striking violation was that the wrong lot number was listed on the label of the bottle containing the Parafon tablets. In addition, the room in which the Parafon tablets were stored was cold and damp, 21 C.F.R. 133.3."

Thereafter, the court fined the corporation and the individual \$1,000 each and sentenced the individual to one day in prison. (49)

NOTICE OF JUDGMENT on Miscellaneous Action

Dietary supplements and vitamin and mineral fortified foods, Washington, Dist. Columbia.

Charged 9-21-66 and amended 9-26-66 by Pharmaceutical Manufacturers Association as representative of dietary supplement manufacturers and marketers, and Abbott Laboratories, American Home Products Corp., Chas. Pfizer & Co., Inc., and 9 other dietary supplement manufacturing and

marketing companies in a suit against H.E.W. Secretary Gardner and FDA Commissioner Goddard for declaratory judgment and injunctive relief: that on 6-18-66, the defendants published an "order" (Part 80) providing for the establishment of formal definitions and standards of identity for dietary supplements and for vitamin and mineral fortified foods, restricting the types of foods to which vitamins or minerals may be lawfully added, and requiring that dietary supplements bear a label statement concerning the amounts of vitamins and minerals supplied in foods and the absence of a scientific basis for routine use of dietary supplements; that the order promulgating Part 80 stated that persons adversely affected may file objections and request a hearing; that the plaintiffs filed objections and requested that no hearing be held because a proposal to adopt Part 80 had not been published; that, prior to the issuance of such "order," there had been no proposal published and no opportunity for comment with respect to the subject matter; that the Administrative Procedure Act and 21 U.S.C. 371(e)(1) required a notice and an opportunity for persons to present their views; and that the promulgation of the Part 80 order irreparably injured the plaintiffs. The plaintiffs prayed that Part 80 be declared null and void and that the defendants be enjoined from instituting a hearing on Part 80 until they: (a) publish a proposal to adopt Part 80, (b) afford all interested persons an opportunity to submit their views, and (c) act after consideration of all relevant matter presented. The matter came before the court on cross-motions for summary judgment. The Court for the District of Columbia found for the Government saying:

"The plaintiffs claim that the Secretary has violated the statutory provisions to which reference has been made by omitting the first stage prescribed by the statute, namely, issuing and publishing a proposal and affording all interested persons an opportunity to present their views thereon prior to the issuance of the order.

"The fact is undisputed that a proposal was submitted. There is a controversy between the parties as to whether the order subsequently issued was broader than the original proposal. This may involve an issue of fact, but the disposition that the Court is about to reach eliminates that issue of fact if it otherwise exists.

"It must be observed that this action, which seeks an adjudication and injunction on the basis that further proceedings in the matter before the Food and Drug Administration are illegal and violative of the statute in that, as stated before, the first stage prescribed by the statute was omitted, does not relate to an adjudicatory administrative proceeding but to a rule making proceeding. The difference is not merely a difference in fact but is a distinction in principle.

"The plaintiffs and all other interested parties will have full opportunity to present evidence and objections at the forthcoming hearings to the same extent that they had in respect to the original proposal. In other words, their rights to object are not affected by what they claim is a violation of the procedure prescribed by statute. Eventually they may have recourse to judicial review in the United States Court of Appeals. To be sure, the statute provides that the remedy by review in the United States Court of Appeals is not exclusive but shall be in addition to, and not in substitution for, any other remedies provided by law. The question, however, is whether the District Court should enjoin the progress of this rule making proceeding. The Court is of the opinion that it would be improvident for it to endeavor to do so.

"It is a general rule that even in adjudicatory proceedings the person aggrieved must first exhaust his administrative remedies and then seek a court review from the final decision. The Court knows of no case, and none has been cited, where an injunction has been issued against the progress of a rule making proceeding.

"As has been stated before, the plaintiffs and all other interested parties have a full and complete opportunity to present evidence and argue objections at the forthcoming hearings." (50)

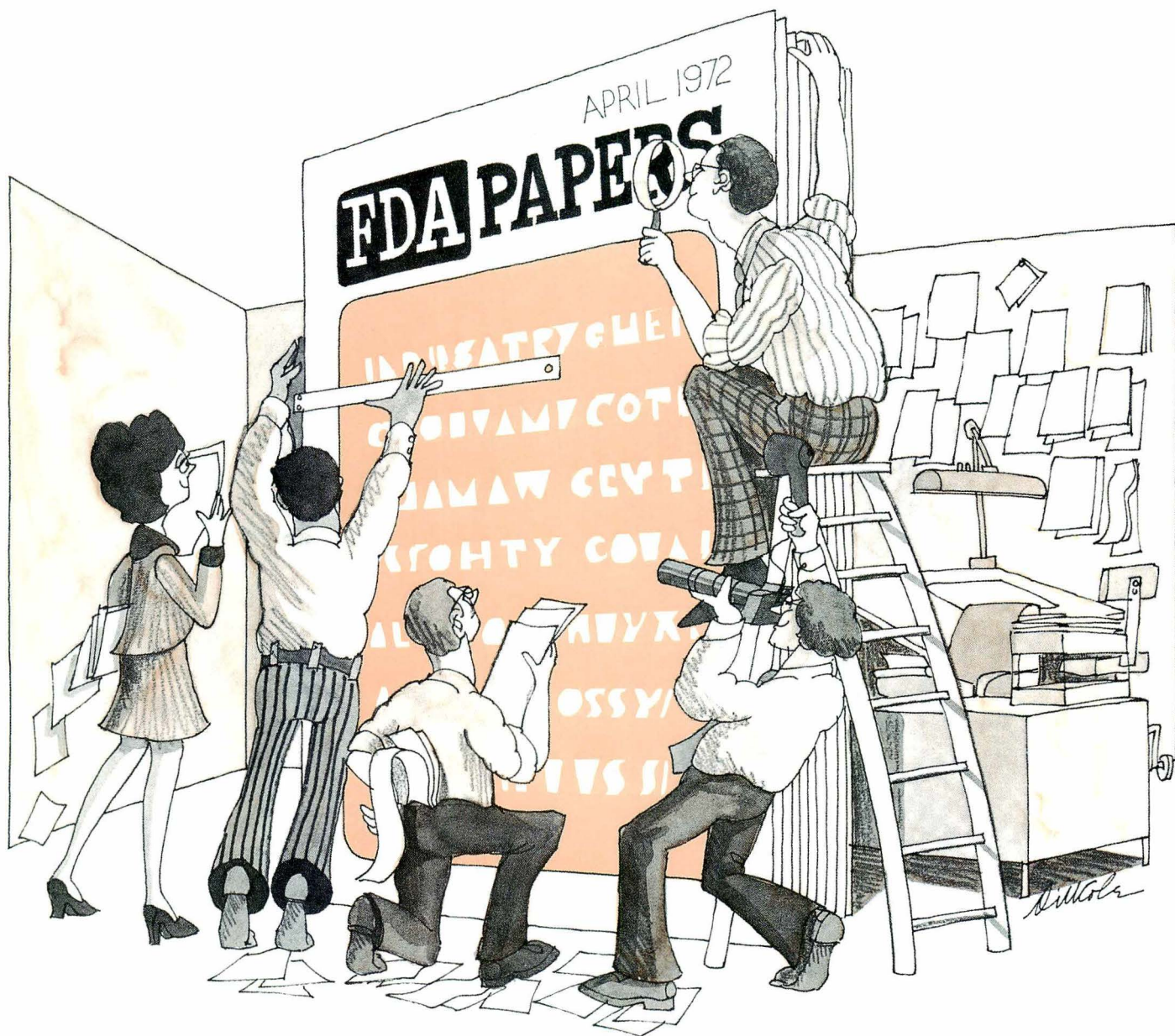
Notices of Judgment are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act and section 13 of the Federal Hazardous Substances Act. Notices of Judgment report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions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

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

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Charles C. Edwards, M.D., Commissioner of Food and Drugs
Washington, D.C. April 1, 1972

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