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ood Drug Cosmetic Law JOURNAL

hanging Regulatory Patterns: New Device Legislation

. . . . . JAMES B. SWIRE

Food Law—International

. . . . . JULIUS G. ZIMMERMAN

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THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis contributions and comments are invited.

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TO THE READER

New York State Bar Association Meeting. The following papers were presented at the 31st Annual Meeting of the Food, Drug and Cosmetic Law Section of the New York State Bar Association, which was held on January 29, 1976 in New York.

"Food Regulation: Quo Vadis?" contains insights on many regulatory problems currently troubling the food industry. Written by *Murray D. Sayer,* the article analyzes the area of food safety from the viewpoint of both consumers and scientists. Mr. Sayer, Assistant General Counsel of the General Foods Corporation, also touches on the subject of overregulation by the government, citing specific examples of confusing regulations. The article begins on page 188.

"Cosmetic Law—Pending Litigation" outlines the issues involved in three court cases brought by members of the cosmetic industry in the District of Columbia federal courts. Written by *Stanley M. Grossmann,* the article begins on page 198 and discusses the background and status of the suits. Mr. Grossmann is with the Legal Department of Pfizer Inc.

James B. Swire analyzes the device bill pending in Congress in his article beginning on page 204. A member of the law firm of Rogers, Hoge & Hills, Mr. Swire predicts the basic structure of the impending law, comparing differences in the House and Senate versions. The article is titled "Changing Regulatory Patterns: New Device Legislation."

Roger M. Rodwin discusses recent regulatory developments in drug law by describing the new regulatory framework of the FDA regarding the marketing of human prescription drugs. "Drug Law—Regulatory Developments" also contains suggestions for new legislation and methods of drug development. Mr. Rodwin, whose article begins on page 211, is Vice-President of Winthrop Laboratories, Inc., a division of Sterling Drug, Inc.

"Food Law—International" is *Julius G. Zimmerman's* report on international food law. Beginning on page 218, the article covers many aspects of the international situation, including recent legislative changes, the availability of text material and the September 1975 meeting of the European Food Law Association. Appended to the presentation is a selected Bibliography of recent articles relevant to this topic appearing in the FOOD DRUG COSMETIC LAW JOURNAL. Mr. Zimmerman, an attorney in New York City, is Editor of Foreign Law of the JOURNAL.

Food Products Workshop. The following papers were presented at the Food Products Workshop sponsored by the FDLI in New York City on October 6—8, 1975.

Howard E. Bauman, Vice-President of Science and Technology in the Pillsbury Company, examines the FDA's nutrition regulations and their effect on label copy and manufacturing processes. Included with the article is a checklist for formula and label compliance to be used as a guide when developing new foods. "Nutrition Regulations in Product Development" begins on page 232.

"Regulatory Survival Kit" is *I. H. Goldenfield's* suggested model for ensuring that manufactured products meet regulatory requirements. Using a hypothetical example, the Regulatory Manager of Quality Assurance for Hunt-Wesson Foods, Inc. shows how a company can make regulatory review a part of product development. Mr. Goldenfield's article begins on page 241.

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Food Regulation: Quo Vadis?

By MURRAY D. SAYER

Mr. Sayer Is Assistant General Counsel of the General Foods Corporation.

ANYONE IN THE FOOD INDUSTRY TODAY must have feelings of disquietude over current developments affecting the industry. These developments stem not from just one area, but from the whole spectrum of areas which impact on the industry, including the consumer, scientific, legislative and regulatory areas. As events develop from day to day, I get the uneasy feeling that all of us—not just industry itself, but those who rely on it and regulate it— are somewhat akin to the populations of lemmings preparing for a mass migration to the sea.

The sea to which we are migrating is, of course, not a watery one, but a sea of chaos within the context of our total food supply. It is exemplified by consumers struggling in a current of concern over the safety and wholesomeness of their foods, by business executives grasping for straws as the shifting tides threaten to engulf them, and by scientists, who are actually in the lifeboat, but don't know which way to paddle to safety.

It is not my intent to spend time baying at the moon, which has little effect other than breaking the silence, although I may end up doing little more than just that. Nevertheless, I believe that where we face problems approaching crisis proportions, it is important to speak of these things even at the cost of being refuted by others who may see the problems differently. Therefore, I propose to discuss a few of the problems which I perceive as matters of concern to the food industry and to the public which it serves. Unfortunately, I can-

not predict how these problems will be resolved since my crystal ball has been recalled for being defective.

Without doubt, the overriding concern today is with food safety. Many consumers have expressed a lack of confidence in the food they eat, in the industry which processes the food, and in the governmental agencies charged with regulating the industry. This lack of confidence is quite understandable when one reviews the plethora of warnings, recalls and delistings which have assailed consumers over the past few years. These include, to mention only a few, cranberries, botulism in soup and mushrooms, mercury in fish, cyclamate, Violet No. 1, diethylstilbestrol, nitrates and, most recently, Red No. 2. These concerns are often reinforced by media which are unaware of the complexity of the issues and only too willing to attribute the situation to the callousness of industry and the compromising of the regulatory agencies.

Present Unhappy Situation

Any responsible member of industry will reject both of those premises. How, then, do we find ourselves in the present unhappy situation? The issue of safety is, of course, a scientific question. With millions of dollars being poured into scientific research, why is there such a crisis over the safety of our food supply? The answers to this question are far more complex than a layman can answer. However, I would like to offer a few observations on the issue.

First of all, science and scientists are much misunderstood by the general public. The public tends to think of science as a body of absolute knowledge and scientists as persons who are all knowing in the application of that knowledge. The supposed proof of this is evident in the miracles that surround us, such as interplanetary research, trips to the moon, jet planes, computers, and so forth. Yet those who must deal with science and scientists recognize that a great many areas of scientific knowledge are not only uncertain, but are often full of conflicting hypotheses and contradictory conclusions. This condition in the sciences does not relate only to food safety. As an example, there is a current scientific crisis concerning the theories about the process by which the sun burns. The long-held theory of fission has been questioned by certain scientific studies, and many new hypotheses are being suggested. So, food science is not the only area in crisis, but its impact is much more imminent than our problems with the sun.

One of the conundrums involved in the science of food safety is that it is impossible to prove that a food or substance is safe. We can prove that a substance is unsafe, or nutritious or has a physiological impact on the body. This is established by specific positive findings. But safety can be established only by the negative, that is, the absence of positive results.

The implication of this is that safety can never be proved, no matter how many tests are run. Even if 100 tests of all kinds are conducted and all the data are negative, all it takes to jeopardize that body of data is test number 101 which develops some positive findings. And test number 101 may even involve totally new protocols or analyses from what had been previously accepted.

Red No. 2

This can lead to a shock such as just occurred with Red No. 2. Consider that situation for a moment. All the safety data had been reviewed by a special toxicological advisory committee in November of 1975. The committee's tentative conclusion was that Red No. 2 was not a hazard. However, the committee did ask for a further statistical review on one of the long-term feeding studies. On December 28, 1975, the Food and Drug Administration (FDA) Commissioner appeared on a nationwide television program on which Red No. 2 was discussed. The Commissioner defended Red No. 2, relying, quite properly, on the scientific data and the judgment of the scientific experts. He called Red No. 2 "the most studied chemical in the food supply" and added that the studies do not show carcinogenicity, mutagenicity or teratogenicity.

Yet barely three weeks later, Red No. 2 was banned, with the attendant shock to consumers, industry and, probably, the scientists themselves. The basis for this astounding reversal was a reanalysis of data of an existing study applying different criteria than had been used before. Being neither a scientist nor in the Commissioner's "hot seat," I am in no way prepared to second guess the Commissioner's decision. But to my layman's mind, it does seem to point out the need for scientists to establish some generally accepted criteria for scientific studies, including the protocols and analysis of data. This does not rule out new test methods or analytical methods, but such new techniques should be studied carefully by the scientific community to determine validity before data from such tests are accepted. Without more carefully defined criteria, we are like players in a ball game where new rules are imposed as the game progresses and the

referees impose penalties for that which was not a violation when the game started. In this case, the penalties are imposed against the public and the industry.

I have one other observation on the scientific front. For a long time, I have wondered if we are not making unfair demands on our scientists. On the one hand, we give them the responsibility of conducting scientific studies and accumulating masses of data. But then we do not give them the opportunity to make a scientific judgment as to whether a substance or a food is safe under the conditions of use. Instead they must play the game of "pin the label on the donkey." Is it a carcinogen, or isn't it? Is is a teratogen, or isn't it? Is it a mutagen, or isn't it?

Cyclamate

Furthermore, they are expected to apply these labels with an absolute certainty not warranted by the nature of the scientific process. An example of this was demonstrated on the December 28 television program which I referred to earlier. In discussing the issue of cyclamate, which was under consideration by a scientific panel, the Commissioner said he would reject a finding of the panel if it concluded that there was a 95 percent probability that cyclamate is not a carcinogen. This would be characterized as a "wishy-washy" answer rather than a clean bill of health and, therefore, a basis for rejection. Yet, this demand for 100 percent certainty is an anomaly where the given premise is that nothing can be proved to be absolutely safe. It seems to me that if the scientists are expected to determine whether our foods are safe or not, they must be given an opportunity to express their judgment and not be required to chase after that elusive goal of absolute certainty.

If food safety and the processes controlling it are paramount in the future, there are other issues which may impact greatly on the food industry. In a recent weekly publication, two separate articles addressed the subject of government overregulation. One article reported the leaving of Lewis Engman as Chairman of the Federal Trade Commission. One of Engman's targets during his tenure as Chairman had been overregulation by government agencies. As he left office, he took the opportunity to take another swipe at all levels of overregulation, including state and local regulation.

In another report on the meat and egg industries by a panel of Massachusetts Institute of Technology researchers to the National Science Foundation, the charge of overregulation was more specific.

In addition to charging that overregulation is adding to product cost, the report stated that:

". . . rigid and frequently outdated standards of identity discourage the development of new or improved products, which would extend the quality and variety of the national protein supply. Other standards, microbiological for example, increase cost to the consumer in the absence of evidence of improved product quality or safety caused by their enforcement."

The charge of overregulation is voiced throughout the land and there seems to be general agreement to the charge by all—except the regulating agencies. The FDA is no exception and it appears we can continue to expect a vast outpouring of new regulations. This phenomenal output of regulations has many reasons. I would like to discuss only a few.

Mass of Regulations

The first is the theory used by the FDA for issuing this mass of regulations. The 1938 Federal Food, Drug and Cosmetic Act contains two sections relating to the issuance of general regulations. These are Sections 701(a) and 701(e). Section 701(a) simply grants authority to promulgate regulations for the efficient enforcement of the Act. Section 701(e), on the other hand, spells out a complete procedure which the Agency must follow when promulgating regulations, including publication of proposals and final regulations, opportunities to comment and to file objections and, if desired, the right to a public hearing. For many years after adoption of the Act, regulations issued under Section 701(a) were considered to be procedural, not substantive, regulations. Only regulations promulgated under Section 701(e) were considered to be substantive, having the full force and effect of law. In short, a violation of a Section 701(e) regulation was considered a *per se* violation of the Act whereas a violation of a Section 701(a) regulation was not.

Three years ago, the FDA announced to the food industry that it had discovered that the Food, Drug and Cosmetic Act was not a law, but a constitution. Under this constitution, the FDA could take whatever action it deemed desirable and necessary unless such action was specifically prohibited by the Act. One of the ways this policy was implemented was by the issuance of substantive regulations, which are not subject to any hearing process. The failure to conform with such regulations is considered a *per se* violation of the Act. True to its word, the Agency has since spewed forth regulations in unprecedented quantity.

The implications of this new-found procedure are tremendous. In the past, whenever disagreements arose between the FDA and the industry over the labeling or composition of a product, the usual way to resolve it was by seizure of the product by the FDA. Both sides would then have to argue their respective positions before the court. The judge would be the final arbiter. During the trial, however, the FDA would have to establish cogent and logical arguments as to why the product violated the Act and not merely a regulation, unless it was a Section 701(e) regulation, such as a standard. Under the new procedure, all the Agency has to do is first issue a new regulation. When it seizes a product which is contrary to the regulation, all it needs to do is to show that the product does not conform to the regulation. Obviously, this procedure is much simpler for the FDA than the old process.

At this time, the question is not resolved as to whether the Agency can use this new regulation-making process to legislate new, substantive provisions of law. The issue is being litigated with respect to one of the new regulations, namely, the Part 102 regulations, more generally known as the common or usual name regulations. At this time, the court has resolved the procedural arguments and is considering the substantive issue itself.

Good Manufacturing Practices

There is, however, a recent case on a closely related issue which, to some degree at least, has gone contrary to the FDA's position. The FDA, in the past, has issued a series of good manufacturing practices (GMP) regulations which, according to the Agency, have the full force and effect of law. Recently, the FDA brought a criminal action against a fishery company for failure to comply with the GMPs. The court held for the fishery. In reply to the FDA's contention that Congress had made it a crime to violate any regulation duly promulgated by the Agency, the court replied as follows:

"But Congress clearly has not chosen this course. I concluded, and I continue in the view, that in each criminal prosecution. . .. the government must prove beyond a reasonable doubt, not that the FDA regulations have been violated, but that the food was adulterated."

This case, being criminal in nature, is not dispositive of the issue but it must be considered at least a temporary setback for the FDA's new procedure.

But this new procedure is only the mechanism by which the Agency hopes to simplify its substantive goals. I would like to talk

about some of the FDA's specific objectives. The Agency has many of these objectives, some of which I do not disagree with and others to which I am very much opposed. I intend to discuss only one of those objectives, a critical one which can have a great impact, not only on many of our present foods, but also on development of new products.

This objective is not contained in a single regulation but is the aggregate of a whole series of regulations, which can be classified under the blanket description of nutritional regulations. It represents, in my opinion, a long-range philosophy in food control which, if ultimately successful, can only stifle new product development. On their face, the nutritional regulations establish a format for labeling nutrients on food packages, a basis for educating consumers on nutrition, and recommendations for adding levels of nutrients to specified foods. However, if I read them correctly, they represent the FDA's attempt to control completely the amounts and the kinds of nutrients which can be added to food, as well as the foods to which nutrients can be added. For those who are not aware of this implication, I would like to explore the history which leads to this conclusion.

Sometime in 1958, I was talking with an FDA inspector about a variety of subjects. At that time, he told me that, at a recent meeting with FDA officials, he had been advised that the Agency planned to put most of the vitamin manufacturers out of business. Neither he nor I understood what was meant by that and pursued it no further. However, over the years, the pattern became clear.

Addition of Nutrients

The first shot came in 1961 when the FDA seized a product called Dextra Sugar. This was regular sugar to which the manufacturer had added vitamins and minerals. The FDA charged in court that the sugar was misbranded since, by the addition of nutrients, the manufacturer was representing to the public that they were deficient in nutrients and that such representation was false because the public was not deficient in nutrients. The court gave the Agency short shrift and threw out the case with the following observations:

"The basic flaw in the Government's case against the product is that it is seeking, under the guise of misbranding charges, to prohibit the sale of a food in the marketplace simply because it is not in sympathy with its use. But the Government's position is clearly untenable. The provisions of the Federal Food, Drug and Cosmetic Act did not vest in the Food and Drug Administration or any other federal agency the power to determine what foods should be included in the American diet; this is the function of the marketplace. Under Secton 403

of the Act, Congress expressly limited the Government's powers of seizure to those products which are falsely or deceptively labeled. As the Supreme Court aptly stated in rejecting a similar attempt to overreach the authority granted by the Federal Food, Drug and Cosmetic Act:

"'In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop. *United States v. 62 Cases, etc.*, 340 U. S. 593, 600 (1951).'"

Not at all deterred, the FDA took a new tack. In 1966, it published a proposed revision of the special dietary food regulations. Incorporated within the framework of these regulations was a proposal to establish standards of fortification for a few specified foods. Then there was a little hooker thrown in. The addition of nutrients to foods other than those provided for in the standards of fortification was prohibited. These regulations went to a hearing in 1968. This hearing lasted until 1970.

Nutritional Regulations

But even as these hearings ground on, there was a new development on the scene. The White House Conference, which was held in December of 1969, discovered malnutrition in the United States. This was seemingly contrary to the FDA's previous position. However, taking its lead from the Conference, the FDA did an about-face. It never republished its nutritional standards. Instead, it began to issue a series of regulations and proposals regarding nutrition, including the nutritional labeling regulations, nutritional guidelines and general principles on nutrition fortification. When one looks closely at this maze of regulations, one sees the little hooker which was thrown in. This time, the hooker does not prohibit the addition of nutrients. What it does do is provide that if any product contains added nutrients and that product is not in the selected categories of products exempted by the FDA, the product must bear the following statement: "The addition of nutrients to this product has been determined by the U. S. Government to be unnecessary and inappropriate and does not increase the dietary value of the food." Obviously, the purpose of such a statement is to discourage a manufacturer from adding nutrients to any food except as approved by the FDA.

This attempt to control added nutrients in food must also be viewed within the context of a web of other nutritional regulations, some of which seem inconsistent and others which seem merely incomprehensible. These include, for example, the nutritional labeling regulations, the imitation regulations, the nutritional quality

guideline regulations, the common or usual name regulations, the dietary supplement regulations, the amino acid regulations and the serving size regulations. Anyone who has tried to correlate even a few of these regulations knows what a maze they represent.

Frozen Heat-and-Serve Dinners

Since these regulations will have a major impact in the development of new products, it might be interesting to develop a new product and see what problems occur. Suppose a company wants to make a frozen heat-and-serve dinner in which the protein component is a slice of plant protein product which tastes like ham and which is made from soy, wheat and egg whites. The synthetic ham slice contains five grams of protein having a protein efficiency ratio (PER) of 80 percent of casein. Under the formula established in the nutritional labeling regulations, this would supply less than ten percent of the recommended daily allowance (RDA) of protein. But the nutritional labeling regulations also require that a product must supply ten percent of the RDA in order to be considered a significant source of protein. The imitation regulations also govern this product but they only require that, to avoid being called imitation ham, the product must be equal in nutrition to ham. But a look at the plant protein regulation shows entirely different criteria. This regulation requires that the synthetic ham slice must have a PER of at least 108 percent of casein plus specified levels of vitamins and minerals not necessarily related to the nutrients in ham.

To meet these criteria, the company's corporate research people devise a solution. They propose to add the vitamins and minerals necessary to increase the PER to 108 percent of casein by adding lysine, an amino acid. This will also enable the product to supply ten percent of the RDA of protein and make it not nutritionally inferior to ham. But there is a food additive regulation governing amino acids, which prohibits the addition of lysine or any amino acid to food unless the product contains at least 6.5 grams of protein. The synthetic ham slice only has 5 grams. So, the researchers suggest putting another gram and a half of protein in the product so that the lysine can be added.

Now the company is ready to add mashed potatoes and broccoli to complete the frozen heat-and-serve dinner. But there is only one problem. There is a nutritional quality guideline regulation governing frozen heat-and-serve dinners, which has an entirely different set of nutritional criteria which the proposed product does not meet.

Furthermore, this regulation requires a calcium-to-phosphorus ratio of one-to-one. More tinkering is done by corporate research and finally all the criteria are met.

Now the company is ready with its frozen heat-and-serve dinner, except that the frozen heat-and-serve dinner regulation requires that the protein source be derived from meat, poultry, fish, cheese or eggs. Synthetic protein sources are not allowed in frozen heat-and-serve dinners. The company could market the product if it calls it an "Imitation Frozen Heat-and-Serve Dinner with Imitation Ham."

Is this overregulation? While the above example is a bit tongue-in-cheek, it is not as farfetched as it might seem. The FDA's approach reminds me of the Greek legend of Procrustes who would force his victims to fit exactly on an iron bed. If they were too short, he would stretch them. If they were too long, he would cut off their feet. It seems to me that the FDA is fashioning a new Procrustean bed to which all new products must be forced to fit.

I have attempted to deal with a couple of significant issues affecting regulation of the food industry. If my analysis is even partly valid and if we continue down these roads, I foresee many problems ahead, not only for the food industry but also for the consumers and the FDA. As I mentioned earlier, my crystal ball has been recalled so I cannot really predict where we are going. I can only ask: "Quo Vadis?"

[The End]

FROZEN DINNER AND SEAFOOD COCKTAIL RULES HELD VALID

Regulations for the common or usual names of seafood cocktail and frozen heat-and-serve dinners were upheld by a federal court against the challenge that the Food and Drug Administration (FDA) had exceeded its rule-making authority. The regulations were properly promulgated through the FDA's general rule-making powers, the court stated, for the purpose of informing consumers about the composition of food. Formal rule-making procedures did not have to be followed because the rules in question did not set definitions and mandatory ingredients but set only mandatory categories of ingredients for inclusion in certain foods. The requirement that seafood cocktail be labeled to state the percentage of seafood ingredients was valid because such information must be disclosed to prevent a food label from being misleading, the court stated. *American Frozen Food Institute v. Mathews.*

CCH Food Drug Cosmetic Law Reporter, ¶ 38,055

Cosmetic Law—Pending Litigation

By STANLEY M. GROSSMANN

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THERE ARE THREE ACTIONS pending in the District of Columbia federal courts which have in common the fact that the respective petitioners in each proceeding are challenging new Food and Drug Administration (FDA) regulatory requirements applicable to the labeling of cosmetic products. This presentation is a brief review of the background and status of these suits, which are:

(1) *Almay and Clinique Laboratories v. FDA et al.*,[1] which deals with the so-called "hypoallergenic" regulations promulgated by the Food and Drug Commissioner last year;

(2) *Independent Cosmetic Manufacturers and Distributors (ICMAD) v. FDA et al.*,[2] which relates to the FDA's final cosmetic ingredient labeling requirements; and

(3) *Cosmetic, Toiletry and Fragrance Association (CTFA) v. FDA et al.*,[3] which concerns new FDA requirements for the labeling of cosmetic fragrance products packaged in self-pressurized containers.

In the *Almay* suit, plaintiffs challenge the validity of an FDA order, published as final in the *Federal Register* of June 6, 1975, regulating the use in cosmetic labeling of words, such as "hypoallergenic" and "allergy-tested." The FDA Commissioner found such terms to impliedly represent to consumers that the product so labeled is safer than other similar-use type products because it will cause fewer adverse skin reactions.

The FDA regulation provides that a cosmetic may be designated in its labeling by the term "hypoallergenic" (or by related claims)

[1] District Court Civil Action No. 75-1135.

[2] Circuit Court Action No. 75-1845.

[3] District Court Civil Action No. 75-1715.

if it has been shown by scientific studies conducted with the product that the relative frequency of adverse reactions (defined as any epidermal reactions) in human test subjects is significantly less than the relative frequency of such reactions in reference products. Reference products are defined as either:

(a) each of any number of similar-use competitive products in the same cosmetic product category, which represent a combined market sale of at least ten percent of the similar usage cosmetic market; or

(b) where the relevant market data are not available, at least two similar-use competitive products selected at random which by trade name or brand designation constitute at least ten percent of the total number of nationally distributed similar-use products.

Under the regulatory scheme, a two-year testing period would be allowed for existing products. All of the manufacturer's test records developed pursuant to the regulation would have to be submitted to the FDA prior to use of the claim. The Agency would make such records available to the public. There is no specific requirement for FDA review and approval of the records and test results. Once a product has been shown to cause significantly fewer adverse reactions than ten percent of its competitive products, it may continue to be labeled as "hypoallergenic" for a period of five years. Thus, it need not be retested immediately upon the occurrence of changes in the formulations or market shares of reference products.

Explanatory Statement

In addition, the regulation requires that the explanatory statement, "Less likely to cause adverse reactions than some competing products," must appear once—and, in certain cases, twice—in each article of labeling. According to the FDA, this latter provision was developed in response to a Federal Trade Commission comment that there is a need for the consumer to be cautioned that the term "hypoallergenic" does not guarantee an absence of adverse reaction.

In promulgating this regulation, the Commissioner relied on the statutory authority of both Section 602(a) of the Federal Food, Drug and Cosmetic Act (which declares a cosmetic misbranded if its labeling is false or misleading in any particular) and Section 201(n) (which supports the proposition that labeling can be misleading by reason of its failure to reveal material facts).

The regulation is issued pursuant to Section 701(a) of the Act and is declared to have the force and effect of law. This conclusion is challenged by the plaintiffs. Plaintiffs also argue that the administrative record certified to the Court does not sustain the Commissioner's definition and application of the term "hypoallergenic" and related terms, his finding that the prescribed test method is feasible and necessary for compliance, and the requirement to submit test data to the FDA. It is further asserted that, in any event, the Commissioner has no statutory authority to require the premarket submission of test data for cosmetics and that neither Sections 701(a), 602(a) nor 201(n) purport to confer that authority.

In the course of this litigation up to the present, both sides have filed motions for summary judgment.

It appears that the central controversy between the parties is that the Commissioner has concluded from the record that hypoallergenic cosmetic claims should be supported by testing on a comparative basis, whereas plaintiffs contend that the complete record will support testing against certain objective standards. They argue that the latter is a more scientifically acceptable procedure, sufficient for public protection, and that the Commissioner has acted arbitrarily and capriciously by imposing the comparative testing scheme.

No date has been set for oral argument. The case is before Judge John Sirica.

ICMAD Suit

The *ICMAD* suit is pending before the District of Columbia Circuit Court of Appeals. In a petition for review, the Court is asked to vacate the final order of the Commissioner of Food and Drugs relating to cosmetic ingredient labeling, and to remand the matter to the FDA for further administrative hearings. An earlier move by the petitioner to obtain a stay of the regulatory effective dates (cosmetic labeling ordered after May 31, 1976 and cosmetic products labeled after November 30, 1976 must be in compliance with the regulations) was denied by the Circuit Court. A separate declaratory judgment action which ICMAD brought in the District of Columbia District Court was dismissed on grounds of lack of jurisdiction. An appeal from this dismissal is also pending before the Circuit Court.

The 1966 Fair Packaging and Labeling Act (FPLA)[4] vests authority in the Secretary of Health, Education and Welfare (and

[4] 15 U. S. C. Sec. 1451 *et seq.*

by delegation, in the FDA Commissioner) to promulgate certain regulations with respect to any consumer commodity which is a cosmetic, as well as commodities which are foods, drugs or devices. The statute mandates that information, such as quantity statements and product identity statements, shall appear on packages of these commodities. In addition, the statute gives to the Secretary discretionary authority to require that the label on each package of a consumer commodity shall bear the common or usual names of the ingredients, listed in order of decreasing predominance, whenever the Secretary determines such regulations "are necessary to prevent the deception of consumers or to facilitate value comparisons."[5]

An exception is made that trade secrets cannot be required to be divulged. In promulgating regulations under the FPLA, the Secretary must follow the procedures of Section 701(e) of the Federal Food, Drug and Cosmetic Act.

In reliance upon his authority under the FPLA, the Commissioner, in 1973, proposed regulations which would, in effect, require package listing of all cosmetic ingredients except flavors and fragrances. Certain limited objections to the proposed regulations were filed within the statutory 30-day comment period. These objections were filed by parties other than petitioner. Later in the year, final regulations were promulgated, except for a stay as to those provisions to which objections were filed. The objections were withdrawn when, in March of 1975, the Commissioner issued an order amending the basic ingredient labeling regulations.

Array of Alternative Methods

The amendments, issued for the most part as final regulations, provided an array of alternative methods of declaring ingredients, and exemptions from the 1973 requirements. It was to this order that petitioner filed its own objections and request for hearing, the denial of which is now being challenged.

With such a background, it is at best unclear that in the petition for review action the Court will resolve fundamental issues such as whether promulgation of a single regulation requiring all cosmetic packages to list ingredients was within the statutory authority. That is, should it have been necessary for the Commissioner to make separate determinations for each type of cosmetic product to the effect that the listing of ingredients is needed to prevent deception

[5] 15 U. S. C. Sec. 1454(c)(3).

of consumers or to facilitate value comparisons? Also, to what extent can the determination that cosmetic ingredient labeling is necessary to prevent deception or to facilitate value comparisons be shown to be supported by evidence of record?

The Commissioner's views pertinent to this point were set forth in the preamble to his October 17, 1973 order, portions of which I quote without further comment:

"(T)he Commissioner concludes that all cosmetics are appropriately considered a single commodity: However, even if the term 'cosmetic' is considered to encompass several separable cosmetic 'commodities,' nevertheless the Commissioner concludes that ingredient labeling is needed for all such commodities and that a comprehensive order governing all such commodities in this respect is most efficient.

"Ingredient labeling can be meaningful in preventing consumer deception by precluding product claims that are unreasonable in relation to the ingredients present and by providing consumers with additional information that can contribute to a knowledgeable judgment regarding the reasonableness of the price of the product. Furthermore, while ingredient identity may not be the sole determinant of a product's value to a consumer, it is one important criterion of a product's value in comparison to others. The presence of a substance to which a consumer is allergic or sensitive, for example, may render the product worthless to that consumer."

In the *CTFA* suit, plaintiff challenges yet another set of FDA cosmetic labeling regulations. On March 3, 1975, the Commissioner issued final regulations which, with limited exceptions, would require the following warnings to appear on the labels of most self-pressurized "aerosol" cosmetics:

"Warning—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal."

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

Warnings

Both warnings are expressly required to appear on the *labels* of cosmetic products. Therefore, pursuant to the definition of "label" in Section 201(k) of the Federal Food, Drug and Cosmetic Act, these warnings must be placed on the immediate product container as well as on any outer retail wrapper or package.

Plaintiff challenges these warning requirements solely as they apply to aerosolized fragrance products and, in particular, to those marketed in containers of four ounces net weight or less. Plaintiff first contends that the regulations are arbitrary and capricious insofar as they are made applicable to those small aerosolized fragrance products. Secondly, plaintiff asserts that the Commissioner exceeded his statutory authority by requiring that warnings must appear on

the "labels," rather than on the "labeling," of aerosolized cosmetics. It is noted as significant that in the one place of the Act—Section 502, which governs misbranded drugs—where Congress specifically addressed the placement of product warnings, it designated those warnings for *labeling*. It should be further noted that the cosmetic sections of the Act do not contain a similar provision with respect to cosmetic warnings. The present regulations were issued as binding, substantive rules, pursuant to Section 701(a) of the Act and in reliance upon Sections 602(a) and 201(n) as authority. Interestingly, Section 602(a) declares a cosmetic misbranded if its *labeling* is false or misleading in any particular. This is in contrast to Section 602(b), which requires specific information to appear on the cosmetic *label*. In response to this point of statutory interpretation, the government refers to Section 201(m) of the Act which defines the term "labeling" to include "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or (2) accompanying such article." Thus, it is argued, since "labeling" includes "labels," Section 602(a) prohibits false and misleading labels.

These and other points of controversy were the subject of oral argument on cross motions for summary judgment at a hearing before Judge Charles Richey on January 12, 1976. Judge Richey ordered the parties to file within a week proposed findings of fact, after which he is expected to rule on the motions. **[The End]**

NUTRITIONAL LABELING FOR SOFT DRINKS DELAYED ONE YEAR

The date by which soft drink labeling must comply with new requirements as to declaration of nutritional values has been postponed for one year by the Food and Drug Administration (FDA). The National Soft Drink Association had requested a stay of the effective date pending resolution of all matters concerning soft drink labeling. The FDA judged that a one-year extension would allow soft drink manufacturers to coordinate label changes and possibly avoid unnecessary labeling expenses that would ultimately be passed on to consumers. The regulation is now applicable to all labeling manufactured after October 31, 1976 and for all products initially introduced into interstate commerce after December 31, 1977. The effective date for labeling changes required by the identity standard for soda water has also been extended to remain consistent with the other labeling rules.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,599, 41,602

Changing Regulatory Patterns: New Device Legislation

By JAMES B. SWIRE

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AMERICA'S FIRST NATIONAL FOOD AND DRUG LAW was not enacted until 1906. Since then, our food and drug laws have changed slowly and only after careful deliberation. After 1906, 32 years passed before major revisions were accomplished in 1938. Then, an additional 24 years passed before the 1962 amendments were enacted.

Were this deliberate process to continue, in decreasing eight-year cycles, we should have to wait 16 years—or until 1978—before major new legislation becomes law. But the present Congress apparently does not possess so fine a sense of historical rhythm. On January 21, 1976, the full Interstate and Foreign Commerce Committee of the House of Representatives took a majestic 26 minutes to approve all 116 pages of H. R. 11124, the Medical Device Amendments Act of 1976. According to current thinking, the bill should get to the floor of the House and be passed within six weeks.

Since the Senate passed S. 510, its version of the Medical Device Amendments Act, in April of 1974 by a vote of 88-5, we may expect a new law to emerge from conference and to be signed by the President this spring.

Historically, this new law may be a bit premature and may be born with some congenital defects that will cause problems in the future. But I can assure you that, unlike most babies, this one will have a full set of teeth at birth. As with most children, this new law will require a great deal of close attention.

We are going to have to pay attention because existing medical devices are numerous and varied in their uses and the development

of new and innovative medical devices is proceeding rapidly. Thus, a great number of existing clients will be affected by this law. Many companies—if not whole industries—will be brought into contact with the Federal Food, Drug and Cosmetic Act and with the Food and Drug Administration (FDA) for the first time.

Growing Awareness

I think this new law will also be significant for another reason. There is a growing awareness among many segments of our society that the present 1938 Act, as amended in 1962, requires major revisions. For example, a well-known drug industry figure recently stated:

> "I have found two major areas of agreement between FDA and those who believe FDA is stifling drug development. First, the cost of drug development has indeed increased. No one can argue that it does not cost drug manufacturers money to comply with higher regulatory standards. . . .
>
> "I also agree that the time needed to develop a new drug has increased . . . I agree it is desirable to reduce the time needed for drug development to an absolute minimum. . . ."[1]

The speaker was not a representative of the Pharmaceutical Manufacturers Association. It was Dr. Alexander Schmidt, Commissioner of the FDA.

What Dr. Schmidt and others have recognized is that the basic format of the current drug law may have to be revised. The concept of "old drugs" having no controls and "new drugs" having total controls is too rigid, providing too little supervision over the "old" and too much supervision over the "new." And the concept of "individual" or "personal" approvals and rights in new drug application (NDA) situations is also being questioned by some as too inflexible.

The fact of the matter is that the trend of regulation is already away from these types of controls. The trend is toward across-the-board rules and regulations:

(1) good manufacturing practices (GMPs) which have the force of law for everyone;

(2) the drug efficacy study implementation review under which the FDA and the National Academy of Sciences-National Research Council established panels by therapeutic classes to evaluate effectiveness;

(3) over-the-counter (OTC) drug monographs which are setting standards for classes of drugs; and

[1] Schmidt, Alexander M., "Toward More Effective Drug Regulation," *FDA Consumer*, pp. 27, 28 (Dec. 1975-Jan. 1976).

(4) abbreviated new drug applications so that expensive, time consuming and unnecessary clinical testing need not be duplicated.

These trends, which reflect a basic dissatisfaction with the current drug law, have been considered in the preparation of the medical device bills now before the Congress. As a result, the new device law will be significantly different in format from the drug law which we have lived with since 1938. Depending on our first few years of experience with the device law, we may well see another major revision in the law, this time in the basic drug law.

Basic Format

So it is important that we understand the structure of the impending device law. Recognize, of course, that it is not yet law and that there are differences—some significant—between the Senate and the House versions. But the two bills are close enough in their major aspects to enable us to predict what the basic format will be.

At the outset, what is a device? The definition in both bills is basically the same. "Device" means:

"...an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory which is —

(1) recognized in the Official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes."

As you will recognize, it is the last clause, pertaining to chemical and metabolic action which is significantly different from the definition in the current law.

Assuming a product is a device, there are then three basic regulatory categories which may apply. First, if there is sufficient information to assure effectiveness and to assure that there is no unreasonable risk of illness or injury, the device is subject only to certain general controls. Those controls include the adulteration and misbranding sections of the law, as well as requirements for registration of producers, record-keeping requirements and GMPs. It is apparent, then, that even a manufacturer who has a device which is recognized as safe and effective is still going to be affected by

this law, for it will be required to register and to comply with device GMPs, along with other requirements.

At the outset, we may expect some controversy over the meaning of the phrase "sufficient information to assure . . . that there is no unreasonable risk of illness or injury." That language appears in the Senate bill. The language in the House version—"does not present a potential unreasonable risk of illness or injury"—is similarly ambiguous. The explication of either phrase will be crucial to the development of the new law. An unduly restrictive interpretation will mean that this law represents no great departure from the often unnecessarily rigid controls in existing practice. A common sense interpretation will enable innovation to continue with concomitant protection to the public.

Standard-Making Procedures

The second category of devices is a bit fuzzier to define. In essence, if you have information of the type required in the first category, but still need performance standards "to assure effectiveness or to reduce or eliminate unreasonable risk of injury," then standard-making procedures will be implemented and, ultimately, the device will have to conform to the final standards. This category represents a substantial and important departure from the present drug law.

Finally, where there is insufficient information to assure effectiveness or to assure that the device will not cause unreasonable risk of injury, and standards are *not* appropriate to reduce or eliminate the risk, then *premarket* scientific review is required. Here, too, the language of the two bills varies somewhat. In either version, however, the most likely area of controversy will arise from disputes over whether standards could be devised which would be appropriate to assure safety and effectiveness. This premarket review category is closely akin to the new drug application (NDA) procedure. And, as in the NDA situation, both bills provide for exemptions for investigational use.

Clearly, if we are to make strides away from the expensive and time-consuming aspects of current NDAs, then the attitude of the FDA, consistent with its responsibilities to the public, must favor the use of general standard setting over the premarket clearance of individual products. Further, it is clear that, if such a goal is to be reached, more flexible approaches to product development must be

devised for those devices which fall within this category of premarket review.

Adequate Scientific Evidence

In this last connection, I have some good news and some bad news. First the bad news. The Senate bill would require a device subject to premarket review to prove its effectiveness by "adequate scientific evidence," defined as:

"...evidence consisting of sufficient well-controlled investigations, including clinical investigations where appropriate, by experts qualified by scientific training and experience to evaluate the effectiveness of the device involved, on the basis of which it could fairly and responsibly be concluded by such experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

Such a provision is uncomfortably close to the definition of "substantial evidence" in the current Federal Food, Drug and Cosmetic Act, a definition which has been a very restrictive one. The good news is that even the Senate bill contains this qualifying language: "unless the Secretary determines that other valid scientific evidence is sufficient to establish the effectiveness of the device."

Also, the House version speaks more simply, and less rigidly, of a "showing of reasonable assurance that the device is [safe or effective] under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof."

There seems little doubt that classification into one of these three basic categories will be of great importance to the device manufacturer. Apparently, there will be a right of appeal immediately upon such classification. As in the present law, such appeal will be either to the Court of Appeals for the District of Columbia Circuit or to the court of appeals in the circuit where the manufacturer has its principal place of business. Final orders promulgating standards and denying or withdrawing approvals are similarly appealable.

The above is a very basic outline of the form of the expected device law. There are other provisions, of course, which are important. Many will be concerned with the transitional provisions in the law. In the Senate version, there appears to be a substantially longer grace period for products already on the market prior to enactment than is provided in the House bill. Both bills make exceptions for "custom devices" and include provisions for "banned devices" as well as for notification of defective devices, and repair, replacement or refund of such defective devices, similar to the provisions in the Consumer Product Safety Act.

Extensive Use of Expert Panels

Also of great significance is the fact that both bills provide for the extensive use of expert panels, both for standard setting and for review of applications under the premarket review procedures. As we have seen with the OTC review, industry participation with such panels is vital and can be highly beneficial toward the development of sound policy.

It has been relatively easy to outline the expected shape of the anticipated new law. It is much harder to predict what the experience will be once the law is enacted. Obviously, much will depend on the attitude of the FDA. I think the Agency will welcome the opportunity to take a more flexible approach to regulation, without having to stretch and distort the law as it has sometimes felt compelled to do under the existing Act. But there is a natural and understandable reluctance on the part of Agency personnel to make close judgments. Under pressures of time or conflicting views, the conservative approach is a convenient fallback. To avoid controversy, it will undoubtedly be easier to place a device under standards, rather than to leave it subject to general controls. Similarly, there is always the option of requiring premarket review rather than standard promulgation.

For example, for the past several years the Agency has become actively involved in the field of contact lenses. While conventional hard plastic contact lenses have been available for decades, the FDA became involved only when the so-called soft lenses first appeared on the market. Because of inherent safety problems, the Agency chose to regulate soft lenses as if they were new drugs requiring NDAs, a procedure given judicial approval in the *AMP*[2] and *Bacto-Unidisk*[3] cases.

Contact Lenses

Having become interested in contact lenses, the FDA then discovered that the industry was involved in the development of new and better hard lenses, using either different types of plastics or variations of the basic plastic which had been in use for many years. The FDA's initial response was an encouraging one. Several years ago, it met with industry groups, agreed that it did not want to stifle innovation in the field, and contracted with a subcommittee of the American National Standards Institute to develop standards

[2] *AMP, Inc. v. Gardner*, 389 F. 2d 825 (CA-2 1968), cert. denied 393 U. S. 825 (1968).

[3] *United States v. An Article of Drug ... Bacto-Unidisk*, 394 U. S. 784 (1969).

for safe and effective conventional contact lenses. Despite the development of such standards by the committee, on which an FDA liaison officer served, the Agency has given indications in the last year that it was backing away from a standards approach and adopting instead a premarket review requirement.

In the case of one manufacturer who has for three years successfully marketed a hard lens made of a slightly different plastic, the Agency has stated that it regards this product as a new drug, despite a lack of any indication that any safety hazard exists. As a result, it has instituted seizure actions against the product. (I should note here that my firm is representing the manufacturer in this dispute.) Also, the FDA has published a proposed policy in the *Federal Register*[4] pursuant to which literally no contact lenses on the market are recognized to be safe and effective. The regulatory posture on the bulk of contact lenses is stated to be unclear depending on the development of more information. The remainder of the lenses on the market are treated for the time being as new drugs, requiring NDAs.

Given the long history of safe and effective use of most of the standard contact lenses, and given the fact that three years experience with over 20,000 patients has revealed no problems—only substantial benefits—with the newer hard plastic, it is discouraging to find that the FDA is inclined to the most rigid of legal approaches.

Lengthy Bureaucratic Hassles

Most contact lens manufacturers, like many other device manufacturers, are small companies without the resources to engage in lengthy bureaucratic hassles. An unnecessarily rigid approach by the Agency will undoubtedly stifle innovation in the development of devices, and, in the long run, will detract from the public good. So, the experience with contact lenses is not encouraging.

But I do not wish to close on a negative note. I think the new device law will provide industry and the FDA with the opportunity to protect the public without stifling creativity. Industry, as well as the FDA, will have responsibility under this law. A cooperative approach by industry groups will do much to foster similar cooperation on the part of the Agency.

If we can make this new law work, we may well be laying the groundwork for a basic and beneficial revision in the existing Act.

[The End]

[4] 40 *F. R.* 44844 (Sept. 30, 1975).

Drug Law—
Regulatory Developments

By ROGER M. RODWIN

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DURING 1975, there were more than a dozen important regulatory proposals issued by the Food and Drug Administration (FDA). Several were intimately tied to legislative changes and many had counterparts at the state levels. Consider the following:

(1) final freedom of information regulations;

(2) DEA proposal regarding screening of employees;

(3) conditions for marketing human prescription drugs;

(4) prescripition drug labeling and advertising regulations;

(5) FDA proposal—Administrative Practices and Procedures;

(6) final regulations concerning the failure to reveal material facts in labeling;

(7) final regulations concerning the marketing of radioactive new drugs and biologicals;

(8) final maximum allowable cost regulations;

(9) petition regarding patient labeling;

(10) final regulations regarding reminder advertisements and labeling;

(11) marketing status of ingredients recommended for over-the-counter (OTC) use; and

(12) proposed good manufacturing practices (GMPs) for devices and large volume parenterals.

Each of these proposals has generated consideration and discussion. There is, however, a basic regulatory philosophy which appears to be emerging from several concepts at the same time. Ironi-

cally, this regulatory development actually began in the United States District Court for the District of New Jersey on January 20, 1975. At that time, Hoffmann-La Roche Inc. instituted litigation against Zenith Laboratories Inc. and its subsidiary Paramount Supply Corp., alleging infringement of plaintiff's patent on chlordiazapoxide. During the course of pretrial discovery, plaintiff learned that the defendants had begun to ship the product in interstate commerce without approval of a new drug application (NDA). On February 27, 1975, Hoffmann-La Roche filed an action against the Secretary of Health, Education and Welfare and the Commissioner of the FDA in the United States District Court for the District of Columbia, seeking a declaratory judgment and injunctive relief. Plaintiff alleged that the FDA had acted contrary to the statutory requirements of the Federal Food, Drug and Cosmetic Act and the rule-making provisions of the Administrative Procedures Act. In essence, plaintiff challenged the FDA's policy of permitting the introduction of a new drug in interstate commerce without first approving an NDA for such drug as required by Section 505 of the Act. In addition, plaintiff sought to declare such a policy void, since it was adopted without notice and deprived interested parties of their right to comment thereon. On March 7, 1975, Zenith Laboratories submitted an NDA for chlordiazapoxide, which was subsequently approved by the FDA. On May 15, 1975, Dr. J. Richard Crout, Director of the Bureau of Drugs in the FDA, made an affidavit in support of the Agency's position in the cross motions for summary judgment.

Dr. Crout's Affidavit

In his affidavit, Dr. Crout described the regulatory program which had been continuing since 1968 and which had been subjected to public, Congressional and judicial scrutiny throughout the last few years.[1] Dr. Crout indicated that the Agency had reached the point of focusing upon those drugs which were rated effective under the Drug Efficacy Study Implementation (DESI) Review Program. These products, approximately 1,400 in number, are presently regulated under the Abbreviated New Drug Application (ANDA) Program. Dr. Crout noted that, over the past five years, the number of such identical and similar drugs has grown in rough proportion to the public's interest in purchasing generic products, which are often less

[1] See *American Public Health Association v. Veneman*, 349 F. Supp. 1311 (DC DofC 1972).

costly than the brand name pioneer drugs. The ANDA regulatory system is "a mechanism between declaring pure 'old' drug status and requiring full NDAs for these drugs. . . . The vast majority of these drugs today can be considered old drugs." The remainder are those with a potential bioequivalence problem.

The balance of Dr. Crout's affidavit proclaimed the FDA's new regulatory philosophy:

"For several years the Food and Drug Administration has been working toward a system under which effective DESI drugs will be regulated under 'old drug monographs'.... Basically a distinction will be drawn between the *general recognition of safety and effectiveness of the generic entity involved* and upon which old drug status is premised, and the *recognition of safety and effectiveness of specific products as manufactured* by specific establishments."

New Regulatory Framework

The formal publication of this new regulatory framework appeared on June 20, 1975, in the *Federal Register,* and contained three sets of related regulations concerning conditions for marketing human prescription drugs. The first of these proposals would add a new Section (310.7) applicable to prescription drug products which were covered by an NDA prior to October 10, 1962 and thus were subject to the effectiveness requirements of the 1962 Drug Amendments. Such drugs which would have been the subject of a DESI notice could be marketed lawfully without submission or approval of either an abbreviated or a full NDA if the applicable DESI notice was published, found effective for at least one indication, and met all of the requirements and limitations established in the DESI notice, including labeling, potency, dosage and manufacturing. In addition, the manufacturer would be required to submit reports of adverse reactions and would have to assure that the drug was being manufactured in accordance with GMPs.

The proposed regulations included a list of approximately 150 drugs which required either full NDAs or abbreviated NDAs. The drugs requiring full NDAs were products dealing with complicated dosage forms and special manufacturing problems, such as aerosols, controlled release drug products, enteric-coated tablets and radiopharmaceuticals. Abbreviated NDAs were required by drugs which raised a question with respect to bioequivalence, which category was further broken down into those requiring *in vivo* testing and those requiring *in vitro* testing only.

Preamble to the Regulations

The preamble to the proposed regulations traced the history of the Agency's treatment of the concept of a new drug from 1938 to present. Principally upon the basis of the Supreme Court's decisions in June of 1973, broadly sustaining the FDA's application of DESI notices to identical, related or similar drug products and upholding the Agency's primary jurisdiction to determine "new drug" status, the Agency concluded that it would proceed with the development of an old drug monograph system for regulating human prescription drugs in a manner similar to the OTC "Old Drug Monograph Approach."

On July 29, 1975, Judge Green granted Hoffmann-La Roche's motion for summary judgment and found the proposed regulatory policy to be defective. Judge Green concluded that the FDA's policy of permitting new drugs to be marketed without an approved NDA contravened the clear statutory requirement of pre-clearance mandated by 21 U. S. C. Section 355 (1970). "The FDA's choice of policy is not within the intendment of the 1962 New Drug Amendments and the legislative scheme they embody. See *American Public Health Assoc. v. Veneman,* 349 F. Supp. 1311 (D. D. C., 1972). Further, the action of the FDA in permitting such marketing of large classes of me-too drugs violates its own regulations. . ." However, Judge Green did reaffirm the Agency's ultimate regulatory authority:

"The Court recognizes that the FDA is to be given the administrative flexibility to make regulations and to determine the new drug status of individual drugs or classes of drugs. See *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U. S. 645, 653 (1973); *National Nutritional Foods Association v. Weinberger*, 512 F. 2d 688, 696-98 (2nd Cir. 1975). Certainly it has the power to promulgate the regulations that adopt a monograph procedure for human prescription drugs similar to that adopted for over-the-counter drugs whereby a drug or drugs may be declared to be no longer new drugs. See 21 C.F.R. § 330.10 (1974)."

The Court sanctioned the bioequivalence and special manufacturing problem regulations but enjoined the FDA from permitting the introduction into interstate commerce, without an approved NDA, of prescription drugs which the FDA has previously declared to be new drugs within the meaning of 21 U. S. C. Section 321(p)(1970).

On September 22, 1975, the Commissioner withdrew the interim enforcement policy for marketing human prescription drug products covered by a DESI notice in light of the court order in *Hoffmann-La Roche, Inc. v. Weinberger et al.* The Agency indicated that its regulatory policy has been reformulated and would be published in the near future.

Novel Regulatory System

On December 15, 1975, Dr. Crout made a presentation at the Third Seminar on Pharmaceutical Public Policy Issues sponsored by the American University College of Public Affairs. In his presentation, entitled "The Drug Regulatory System of the U. S. and Its Impact on Innovation," Dr. Crout characterized his thoughts as "purely personal." But they appear to be a sequel to prior Agency proposals and recent judicial opinions. They may be a prophecy—legislative as well as regulatory. Under Dr. Crout's novel regulatory system, the concept of a new drug would be replaced by the concept of a "public standard-manufacturer's license" with unequivocal FDA pre-clearance authority for new drugs and generic products. A drug could be generally recognized as safe and effective (not a new drug) but could not be manufactured unless and until the manufacturer had received a license to make that specific drug. Recall Dr. Crout's affidavit distinguishing between "old" drug status and the safety and efficacy of a specific product manufactured by a specific establishment. A variety of concepts are borrowed from the antibiotic regulations and the ANDA programs. The development of specific GMP regulations for specific types of products is an integral part of this new licensing system. Dr. Crout discarded the new drug-old drug concept as "a regulatory failure" having no scientific basis. Under the new system,

"The innovator would investigate a new drug under the IND procedures until he has sufficient animal and clinical data to support the safety and effectiveness of the drug. At that point he would submit to the FDA a petition for a drug monograph, which, if approved, would be adopted by a regulation to serve as a permanent public standard for the drug."

Thereafter "the innovator and all new manufacturers would each submit an application for a manufacturer's license, which would be considered as a private license under the law. . . . Holders of [such license] would be held responsible for reporting adverse effects, for keeping their labeling up to date, for producing the drug in conformance with GMP's etc. . . ."

New for New Legislation

Dr. Crout, acknowledging the need for new legislation, suggests:

(1) For Rx drugs: Turn all approved, full NDAs into "drug monographs" and all ANDAs into manufacturer's licenses. Bring all non-NDA'd drugs into this system over a period of five years.

(2) For OTC drugs: The monographs being developed would become "drug monographs" and the current drug listings would be the basis for manufacturer's licenses requiring pre-clearance in certain circumstances.

(3) Elimination of the concept that animal and human data related to safety and efficacy are trade secrets even during the investigational new drug phase of drug development.

(4) Adoption of a regulatory system for assuring quality control of animal and human data submitted to government.

(5) Improvement of surveillance systems over marketed drugs and an increase of the FDA's authority to deal with problems of marketed drugs, including the absolute authority to remove from the market drugs which are inferior to others on relative safety grounds.

(6) Revision of investigational new drug regulations with closer monitoring and control by the FDA.

This proposal suggests that a manufacturer could anticipate "sharing" the results of its research with its competition. Thus, the proposal merits close examination of its probable impact upon investment return and the economics of industry-sponsored pharmaceutical research. During the decade of the 1950's, the development cost of a new chemical entity was estimated to be approximately $1 million. That figure—average discovery cost for a new chemical entity—today is probably closer to $20 million.[2] Calculations of average patent life and average sales of such drugs for the respective periods in question indicate that the average anticipated yield from private investment in drug research has dropped substantially from almost twelve percent before the 1962 Amendments to less than four percent in the early 1970's. Corporate management can hardly justify such investment at a time when high grade bonds and government-insured investments yield nine percent.

Several alternatives should be objectively considered:

(1) Drug research and development does not have to continue at the same pace as the last three decades.

(2) Drug research and development should be conducted principally by academic institutions supported by government and private grants.

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[2] See Schwartzman, *The Expected Return from Pharmaceutical Research.*

(3) Drug research and development should be conducted principally by the government through a government-owned drug company.

(4) The National Institutes of Health (NIH) should develop those drugs which could never justify investment return under any regulatory program.

Dr. Crout recommended several options under Category No. 4, all of which have certain advantages and disadvantages. In essence, however, I would expect general agreement concerning certain research and development, which should be undertaken principally by NIH, particularly in those categories involving "little commercial value." On the other hand, a similar suggestion with respect to most research or a regulatory scheme which would or could substantially discourage much private research and development of new medicines warrants close scrutiny prior to implementation, in view of the medical, scientific, socioeconomic and political consequences of such a system. **[The End]**

INTRAOCULAR LENSES WILL BE SUBJECT TO NEW DRUG REQUIREMENTS

On the basis of clinical data, recommendations of two advisory committees and a review of published literature, the Food and Drug Administration (FDA) has determined that intraocular lenses are not generally recognized as safe and effective and therefore require premarket approval. Beginning October 8, 1976, intraocular lenses will require either an approved new drug application or a Notice of Claimed Investigational Exemption for a New Drug. The FDA provided the 180-day period prior to enforcement of its policy so that manufacturers, distributors and investigators of intraocular lenses may have time to achieve compliance.

Developed as an alternative to eyeglasses and available for experimental use since 1949, intraocular lenses are intended to replace surgically the lenses of the human eye. The use of intraocular lenses declined following a report in 1953 that the employment of such lenses is inferior to conventional surgery in treating cataracts. A question was raised in 1969 over the safety and effectiveness of intraocular lenses in the treatment of aphakia (absence of the natural lens of the eye), and since then there have been indications that the use of intraocular lenses may give rise to a number of complications.

Interested persons have until June 7, 1976 to submit written comments on the implementation of the new drug requirements for intraocular lenses and specifically on the development of guidelines for the testing and clinical investigation of such lenses.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,606

Food Law—International

By JULIUS G. ZIMMERMAN

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THIS IS THE THIRD TIME that I have had the privilege of reporting to the Food, Drug and Cosmetic Law Section of the New York State Bar Association on the progress of foreign food laws and the international situation in this field. My first two reports were made in 1959 and 1969 with each report covering the preceding decade.[1] Now another seven years have passed and we can look back on a quarter of a century which virtually witnessed the development of modern food law. In my last report, I described the outstanding characteristic of the period as an "explosion of food law" which had its beginning at about mid-century after the end of the Second World War, a war that had sparked an almost incredible development of science and technology on a worldwide scale. In fact, the pace of this technological development seems to be accelerating, as does the growth of food law. A number of reasons explain this trend:

(1) the population explosion of the post-war era;

(2) the development of modern transportation;

(3) the development of the news media facilities which transmit information to all parts of the world within minutes;

(4) the electronic collection and processing of data by computer;

(5) the development of modern packaging methods for foods; and

(6) the growing interest and awareness of consumers in the field of nutrition and the concept of a balanced diet.

[1] Zimmerman, J. G., "Progress of Foreign Food Law," 14 FOOD DRUG COSMETIC LAW JOURNAL 189 (March 1959); Zimmerman, J. G., "International Food Law Developments in the Past Decade," 24 FOOD DRUG COSMETIC LAW JOURNAL 184 (April 1969).

In recent years, three additional reasons reinforced this trend:

(1) an ever-growing number of new sovereign nations;

(2) the ever-widening scope of legislation affecting food; and

(3) the piecemeal method of legislating which prevails in many countries.

(1) *Growing Number of Sovereign Nations:* In 1945, when the charter of the United Nations was signed in San Francisco on June 26, there were 51 original member nations—including the United States—which ratified the charter. By December of 1975, that number had increased to 143. Thus, the membership of the United Nations almost tripled during the past 30 years. This was due primarily to the transformation of former colonies into independent countries. All these new countries are issuing new legislation of their own in an increasing number of languages, which complicates the study of food law on a worldwide basis.

(2) *Widening Scope of Legislation:* The scope of legislation affecting food and food law has also widened considerably in recent years by the growing demands for the additional protection of the health and pocketbook of the consumer, the protection of environment, etc. Much of this concern goes beyond the boundaries of "food law" in the strict meaning of the term.

(3) *Piecemeal Method of Legislating:* Because much of recent legislation has been prompted by political and/or economic pressures in a fast-changing world, we notice in many countries a proliferation of laws and regulations which overlap both in substance and in the assignment of administrative jurisdictions. However, during the past 15 years, a few countries have introduced comprehensive legislative reforms in the field of food law, namely Italy (1962), Belgium (1964), Sweden (1971), Denmark (1973), the Federal Republic of Germany (1974) and Austria (1975).

Any comparative study of food law on a worldwide scale depends on the availability of at least the text material of laws and regulations which deal with the production, manufacture, processing, packaging, labeling and distribution of food in its various stages from raw materials to the packaged item offered to the consumer. Here in the United States, we are fortunate in having a very well-developed and up-to-date system of government and private publications. This makes it easy for the scholar—as well as for interested members of the public—to obtain or to peruse the original legislative texts, court

decisions, commentaries, etc. which form the body of the food, drug and cosmetic law (both federal and state) in force in the United States. Numerous professional journals supplement this information, as do the various annual Symposia, such as the Educational Conference sponsored by the Food and Drug Law Institute (FDLI) in cooperation with the Food and Drug Administration. The proceedings are published in the FOOD DRUG COSMETIC LAW JOURNAL, which, incidentally, published 129 articles about foreign and international food law during the past 22 years. Its entire May 1973 issue was devoted to papers presented at the international Conference held in Budapest, Hungary on November 3 and 4, 1972 under the sponsorship of the FDLI.

Rely on Translations

A very good documentation about food and drug law can be found also in Canada, the United Kingdom and other developed countries. But, because so many different languages are used in this field, one has to rely on translations into English and/or French, the most commonly known and used languages in the field of foreign and international food and drug law. Such translations are frequently very difficult to obtain. There are few information centers or law libraries which have a complete collection of national *Official Gazettes,* not to speak of specialized material dealing with food law and related matters. Highly specialized in this field are the World Health Organization (WHO) in Geneva and the Food and Agricultural Organization of the United Nations (FAO) in Rome, particularly the Legislation Branch of the FAO. However, their publications, which deal with food law proper and which are available to the general public, are frequently only digests (WHO International Digest of Health Legislation, a quarterly) or excerpts (FAO Food and Agricultural Legislation—semi-annual) and are not meant to be a complete and up-to-date record of food legislation. They are, however, available in an English edition.

The FAO is also publishing a series of legislative studies (not available for purchase) which includes such titles as No. 4 "Legal Systems for Environment Protection (Japan, Sweden, United States) by P. H. Sand (1972), and No. 7 "An Outline of Food Law—Structure, Principles, Main Provisions" by Alain Gérard (1975).

Gérard's study contains an appendix with a bibliography on food law listing works in English, French and German, as follows:

(1) works on food law in general;

(2) the work of international organizations—selected periodical publications, reports and miscellaneous documents;

(3) specialized food law journals;

(4) monographs, selected books, studies and articles—

(A) international law and comparative law;

(B) national law (Belgium, Canada, France, the Federal Republic of Germany, India, Italy, Japan, Sweden, Tunisia, Turkey, the United Kingdom and the United States).

Comprehensive Study of Comparative Food Law

At this point, special mention must be made of the first comprehensive study of comparative food law ever made, under the joint authorship of the late Professor E. J. Bigwood and Dr. Alain Gérard (Brussels University Food Law Research Centre). It was published in four volumes (1967—1971) under the title "Fundamental Principles and Objectives of a Comparative Food Law" by S. Karger in Basel. This study covers the food laws of 13 West European countries, Canada and the United States.

The Food Law Research Centre in Brussels has just completed another very important comparative study which is being published in loose-leaf form by Elsevier Scientific Publishing Company in Amsterdam and New York. It is entitled "Food Additives Tables" and provides a comparative survey of the legal regulations governing food additives in the 20 most important countries exporting and importing food products: 16 West European countries (Austria, Belgium, Denmark, Finland, France, the Federal Republic of Germany, Ireland, Italy, Luxemburg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom) and Canada, Israel, Japan and the United States. This work will consist of one volume of about 800 pages to be published in four parts and to be completed by the end of 1976. After completion, the work will be kept up-to-date by publication of annual supplements.

The growing interest in the study of comparative food law in Europe illustrates the fact that, in spite of all the efforts by governments and international organizations to "harmonize" the food laws of the individual countries, many differences still continue to exist, which is a great obstacle to international trade in food, a most undesirable situation in a world where no single country is completely self-sufficient with respect to its available food supplies. There are few fields of law with a greater diversity of national legislation than

food law. This is due to differences in the constitutional, administrative and general legal background and the degree of industrialization and technological development which, in turn, depends on whether a country is primarily a producer and exporter of agricultural raw materials or engages in the manufacture, processing and packaging of food products, or both. A higher industrialization requires a more sophisticated law.

Combination of Food and Drug Law

One of the most striking differences in the national food laws is the scope of what products are being regulated under this topic. In the United States, the basic Federal Food, Drug and Cosmetic Act regulates food, drugs, devices and cosmetics. The combination of food and drug law in the basic legislation is also the tradition in many countries of the British Commonwealth, but not on the European continent.

The Federal Republic of Germany, for instance, promulgated, on August 20, 1974, a comprehensive law intended to completely reform the existing Food Law Act of January 17, 1936 as amended. This new law, which came into force on January 1, 1975, authorized the Minister of Youth, Family and Health, in cooperation with the Minister of Nutrition and Agriculture, and the Minister of Economy to implement the law by regulations and to invalidate all obsolete and conflicting provisions which still may be on the statute books. The new Act is entitled "Law on the Traffic with Foods, Tobacco Products, Cosmetics and other objects of daily use" and covers specifically foods (whether raw or processed) with their edible wrappings, additives, tobacco products intended for smoking, chewing and snuffing, cosmetics, and objects and wrappings which come into contact with foods, cosmetics, tobacco products or the human body, not just casually, such as clothing, bed linen, bracelets, frames for eyeglasses, toys, cleaning products for household use and insecticides. This list does not include any items which may fall under the separate German Drug Act.

Legal Terminology

Another sector with great diversity is legal terminology. Thus the term "food additive" or its equivalent in foreign languages is in universal use but the definition differs in many countries. The German Food Law Act of 1974 abolished the concept of "foreign substances" of the 1936 Act and introduced a new concept of "food additives" in Article 1, Section 2 which reads as follows:

"Additives, in the meaning of this law, are substances which are intended to be added to foods to influence their condition or to endow them with certain characteristics or effects; not included in this definition are substances of natural origin or substances which are chemically identical with natural substances and are generally considered by the public as being used primarily because of their nutritional, olfactory or taste value, or as luxury items. Not included are drinking and table water."

This definition differs from the official definition of "food additive" for the purpose of the "Codex Alimentarius" which reads as follows:

"*Food additive* means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include 'contaminants' or substances added to food for maintaining or improving nutritional qualities."[2]

Both definitions differ from the definition in Section 201(s) of the Federal Food, Drug and Cosmetic Act. One has to keep this problem of definition in mind when making a comparative study of "additive" regulations. Virtually all countries have now adopted the principle of "positive lists" which means that only the use of additives which have been specifically authorized by regulation is permitted.

Progress of International Harmonization

Ever since the creation of the United Nations and its specialized agencies FAO and WHO, concerted efforts have been made on regional and worldwide levels to bring about a harmonization of food laws. I gave a historical overview of this development in my two previous reports to this Section and in a special report to the Inter-American Bar Association (IABA) in Quito, Ecuador, in 1972.[3] The progress of harmonization in the European Economic Community (EEC) is recorded in the loose-leaf reporter service of Commerce Clearing House, Inc. and published in the English language.[4]

[2] Procedural Manual of the Codex Alimentarius Commission, p. 26 (4th Ed.)

[3] Zimmerman, J. G., "Harmonization of Food Laws and Food Standards in Latin America," 27 FOOD DRUG COSMETIC LAW JOURNAL 645 (Oct. 1972). See also Bledel, Enrique E., "Food Regulation in Latin America," 28 FOOD DRUG COSMETIC LAW JOURNAL 585 (Sept. 1973).

[4] See also Gérard, Alain, "Food Law in the Common Market," 27 FOOD DRUG COSMETIC LAW JOURNAL 483 (Aug. 1972).

The task of developing worldwide food standards is now primarily concentrated in the Joint FAO/WHO Codex Alimentarius Commission, the organization and function of which is described in a Procedural Manual (fourth edition) published by the Commission. At the time of its first session in 1963, it had some 30 members, mostly developed countries. By 1976, its membership had increased to 114 countries of which number more than two-thirds are developing countries. Altogether the Commission has had ten sessions, the last one in July of 1974. The eleventh session is scheduled for March of 1976. Detailed reports of each session are published with a summary of the activities of its various committees. Among its subsidiary bodies are six Worldwide Codex General Subject Committees, eleven Worldwide Codex Commodity Committees and three geographically limited Coordinating Committees for Europe, Africa and Latin America. An additional Committee for Asia is in the process of being formed. These coordinating committees explore the need for and the practicality of regional harmonization on a continental scale.

The procedure for the elaboration of worldwide and regional Codex standards provides for eleven steps in accordance with the Procedural Manual. Step nine is the *recommended standard* which is sent to all member states and associate members of FAO and WHO for acceptance in accordance with the acceptance procedure laid down under the General Principles of the Codex Alimentarius which provides for three options: (1) full acceptance; (2) target acceptance; and (3) acceptance with specified deviations.

International Standards

According to a report prepared by G. E. Kermode, Chief of the FAO/WHO Food Standards Programme for the European Food Law Association (EFLA) Conference in Parma (September of 1975), so far 70 international standards have been finalized and adopted by the Commission and have been or will be sent to governments for acceptance. An additional 40 international standards for milk and milk products have been elaborated and adopted by the joint FAO/WHO Committee of Government Experts on the Code of Principles concerning Milk and Milk Products, a subsidiary body of the Commission, and sent to governments for acceptance. Acceptances have been and continue to be forthcoming. I refer for details to the Session Reports of the Codex Alimentarius Commission and to the December 1975 "List of Standards, Codes of Practice and other Documents al-

ready adopted by the Codex Alimentarius Commission and those under Elaboration."[5]

Another very valuable source of information about regional developments are the professional associations. In the western hemisphere, there is the IABA which meets every two years. It last met in Cartagena, Colombia, in September of 1975. Since 1957, it has had a special section (now a separate Committee XIX) for food and drug law.

I would like now to present a special report about EFLA, a new professional association whose first international Conference was held in Parma, Italy on September 28 and 29, 1975.

The European Food Law Association

The EFLA was created on May 4, 1973 in Brussels as an international nonprofit association with a scientific purpose under Belgian law. Its Constitution was adopted by its first General Assembly and approved by Belgian Royal Decree of October 8, 1973 which gave it the status of legal entity. Its French language name is "Association Européenne pour le droit de l'Alimentation" (AEDA).

The objectives of EFLA are described in Article 2-1 as follows:

"to contribute in Europe, by all appropriate means: (a) to a better knowledge of food law considered as a specialized sector of the general law; (b) to the development of food law and to its international harmonization with due regard to its interdisciplinary character and to its particular role in the field of consumer protection."

It is to serve as:

(1) a permanent structure for cooperation in considering current food law problems;

(2) a permanent structure for information and consultation by the spreading of information in the field of food law, the publication of reviews, monographs or scientific papers, the organization of conferences and seminars, and finally cooperation, as a consultative international association, with organizations and administrations endowed with political responsibility;

(3) the framework for responding to requests to address international organizations, or governments, with recommendations that could influence the evolution or harmonization of food law.

The EFLA is meant to be an *independent* (not a pressure group), *scientific* (nonprofit) and *consultative* (it has no responsibility or power in the political or economic fields) organization. While it is primarily

[5] Document CX/GEN 75/1.

concerned with the evolution of food law in Europe, it welcomes co-operation with any person or institution, public or private, national or international, even if established outside Europe, that pursues similar aims.

The First International Congress of EFLA took place in Parma, Italy on September 26 and 27, 1975. It was attended by more than 100 members of EFLA and numerous guests from nine West European countries, Poland and the United States, including high government officials concerned with health and food legislation and representatives of national and international associations and organizations such as FAO, WHO, EEC, BENELUX and Council of Europe.

The morning session of September 26, chaired by Dr. D. M. Caponera, Chief of the Legislation Section of FAO, was devoted to general addresses by Dr. R. Piccinino, the President of the Association, who stressed the necessity of harmonizing the food laws, and Professor M. J. L. Dols, Vice-President of EFLA who read a message from Professor E. J. Bigwood who regretted not being present on account of illness. Also read were several other messages of greetings from WHO, EEC, Council of Europe, the FDLI in Washington (Mr. Daniel F. O'Keefe, Jr.) and officials of the Italian Government and the City of Parma, notably the Chamber of Commerce which had contributed greatly to the organization of this Conference.

Consumer Protection and Food Labeling

Following these introductory remarks, Dr. D. Eckert, Ministerial Dirigent of the Federal Ministry of Youth, Family and Health in Bonn, reported about "New Developments in European Food Legislation." Such developments proceeded at an accelerated pace during the past 15 years, resulting in comprehensive new food acts in Italy (1962), Belgium (1964), Sweden (1971), Denmark (1973), the Federal Republic of Germany (1974) and Austria (1975) with the emphasis on consumer protection and food labeling. Comprehensive new labeling regulations were issued in the United Kingdom (1970), Sweden (1971), France (1972), Austria (1973) and Norway (1975). A very important Directive on Food Labeling is now being prepared in EEC. The main topics under discussion are: (1) the complete list of ingredients; (2) the date marking; (3) nutritional labeling; and (4) claims.

The afternoon session of September 26, chaired by Professor M. J. L. Dols, former President of the FAO/WHO Codex Alimentarius Commission, was devoted to the topic of "Drafting and Acceptance

of International Food Standards." Professor Alain Gérard, Secretary General of EFLA, presented a detailed paper on the "Juridical and Institutional Aspects" of this procedure which discussed: (1) the general theory of drafting and acceptance of international food standards; (2) the role of the international organizations in the field of standardization of food products, namely:

Inter-governmental organizations

Joint FAO/WHO Codex Alimentarius Commission;

Economic Commission for Europe (ECE/UN);

Organization for Economic Co-operation and Development (OECD);

Council of Europe;

European Economic Community;

BENELUX Economic Union;

International Olive Oil Council (COI French);

International Vine and Wine Office (IWO) (OIV Fr.);

Non-governmental organizations

International Organization for Standardization (ISO);

International Dairy Federation (IDF) (FIL Fr.);

International Organization of Consumers Unions (IOCU).

The second day, September 27, was devoted to the subject of "Reception" or incorporation of international food standards within the national laws of the individual countries. The morning session was chaired by R. A. Dehove, member of the Council of EFLA and former Director of the Central Laboratory of the Ministry of Agriculture of France in Paris. The first paper was a report by Robert Delville, Director of European Affairs of Coca-Cola Europe, on the "Legal and Institutional Aspects" of such Reception. The procedure differs depending on the organization which elaborated the international standard, such as the Joint FAO/WHO Codex Alimentarius Commission, EEC, BENELUX Economic Union or ISO. Mr. Delville reviewed specifically the procedure in the United Kingdom, France, Germany and BENELUX, but concluded that the acceptance of international standards must overcome many difficulties based on political or economic considerations and the different historical backgrounds which account for the peculiarities of the individual national laws. The second speaker was Professor R. Monacelli of the Superior Institute of Health in Rome, and Secretary General of the Italian

Society of Food Science, who spoke about "The Scientific, Technological and Social Aspects" of Reception.

Afternoon Session

The afternoon session, chaired by Dr. R. Piccinino, had several special problems on the agenda: (1) a paper on "Canned Products" by G. Jumel, Director General of the National Chamber of the Canning Industry in Paris; (2) a paper about "Meat and Meat Products" by Dr. H. Schulze, lecturer at the Veterinarian Faculty of the University of Munich; and (3) a paper on "The Appellations of Origin" by G. P. Mora, President of the Consortium of Parmigiano and Reggiano Cheeses in Parma.

In addition to the papers mentioned on the agenda and read during the Conference, the participants received a number of papers which had been prepared specially for this Conference:

(1) "The Elaboration of International Food Standards by the FAO/WHO Codex Alimentarius Commission" by G. O. Kermode, Chief, FAO/WHO Food Standards Programme;

(2) "The Harmonization of National Legislations in the EEC" by E. Gaerner, Principal Administrator, Commission of Agriculture of EEC in Brussels;

(3) "The Elaboration of International Food Standards within the Framework of the Partial Agreement of the Council of Europe" by Dr. O. Messer, Deputy Director of Economic and Social Affairs; and

(4) "Activities of the United Nations Economic Commission for Europe in the Field of Agricultural and Food Trade Standards," an extract from a document published by ECE/UN[6];

(5) individual reports about Reception in Austria, Belgium, the Netherlands, Luxemburg, France, Germany, Italy, Denmark, Finland, Ireland, Norway, Spain, Sweden, Switzerland and the United Kingdom.

All the papers presented at the Parma Conference were in French or English. Some were read in Italian but simultaneous translations into French and English were provided during the sessions.

Tentative plans were made for some regional meetings in 1976 and a full scale Conference in 1977.

[6] AGRI/WP. 1/3.

APPENDIX

Food Law—International

Selected Bibliography of Publications in the English Language—Articles published in the FOOD DRUG COSMETIC LAW JOURNAL*

Supplement

(101)	International Aspects of Food and Drug Legislation (Selected Bibliography) by Julius G. Zimmerman	July	1971	303–322
(102)	Control of Television Advertising in Great Britain by Peter Woodhouse	August	1971	328–333
(103)	The Changing Complexion of the Food Industry in the Common Market by Paul P. Ashley	July	1972	460–464
(104)	Reaching the Common Market Consumer by Julius Green	August	1972	468–482
(105)	Food Law in the Common Market by Alain Gérard	August	1972	483–501
(106)	Harmonization of Food Laws and Food Standards in Latin America by Julius G. Zimmerman	October	1972	645–650
(107)	A Food Lawyer's Report on the Eighth Session of the Codex Alimentarius Commission—Critique and Targets for the Future by Lawrence I. Wood and Stephen A. Weitzman	October	1972	651–656

*For items 1—100, see Zimmerman, Julius G., "International Aspects of Food and Drug Legislation," 26 FOOD DRUG COSMETIC LAW JOURNAL 303 (July 1971).

[The End]

Nutrition Regulations in Product Development

By HOWARD E. BAUMAN

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THIS IS BASICALLY A REVIEW of the highlights of a number of nutritional regulations of the Food and Drug Administration (FDA), and some of the effects that they will have on label copy.

We, basically, start with Section 1.17 which is entitled, "Food, Nutritional Labeling." It must be remembered that nutritional labeling is strictly a voluntary labeling situation wherein the company has a choice of putting nutritional information about the food product on the label. However, if this is done, the information given must conform to the requirements of Section 1.17. For instance, if vitamins, minerals or protein are added to a product or any nutrition claim or nutrition information (other than sodium content) is on the label or in the advertising for the food products, the label must conform to Section 1.17. There are some exceptions. For instance:

(1) infant, baby and junior-type foods are covered by Section 125.5 and dietary supplements;

(2) any food represented for use as the sole item of the diet is covered by Part 125;

(3) foods that are used only under medical supervision are not covered;

(4) iodized salt is covered by a separate section;

(5) a nutrient that is included in a food solely for technological purposes (such as the addition of ascorbic acid to cured meats to assist in the prevention of the formation of nitrosamines) would not trigger nutrient labeling;

(6) a standardized food that contains an added nutrient such as enriched flour is an exception;

(7) food products that are shipped in bulk for use in the manufacture of other foods are not covered;

(8) a food product that contains added vitamins, minerals and so forth for which a nutritional claim is made on the label but the product is supplied only for institutional food service use (This part does require, however, that the manufacturer or distributor must provide the nutrition information directly to the institutions on a current basis);

(9) a decision about fresh fruits and fresh vegetables is still pending.

If a manufacturer does not fit all the exceptions when it makes a nutrition claim, it will have to comply with Section 1.17, which very explicitly tells what must be on the label and where on the label it must be. First of all, all the nutrient quantities, including vitamins, minerals, calories, protein, carbohydrate and fat, must be declared in relation to the average or usual serving. If the food customarily is not consumed directly in relation to an average or usual portion, another column of figures may be used to declare the nutrient quantities in relation to the average or usual amount that is consumed on a daily basis. However, the same format must be used in both cases.

Definitions

There is a definition of the term "serving," as well as of the term "portion," which primarily states that the expression shall be in terms of the convenient unit of food or measure that can readily be understood by purchasers of the food. Permission is given to use metric measurements, such as five milliliters or X number of grams, etc. The declaration of the nutrient quantities must be on the basis of the food as packaged but it is possible to add another column of figures to declare the nutrient quantities on the basis of the food as consumed after cooking or after whatever other preparation there may be. This would allow the use of an additional column in cases when eggs or milk are added to the product and the finished product nutrient content represents the combination of the base product plus the added products.

The regulations very carefully define how the information is to be specified on the label. They state how to determine calories, protein,

carbohydrate and fat content. They explicitly state how those determinations must be calculated for the label. They also allow the fatty acid composition to be declared. This information, which is defined in Section 1.18C, must be placed on the label immediately following the statement of fat content. Any additional information about fat content should also immediately follow the statement on fat content and fatty acids. If sodium is declared, it must follow the statement on fat content.

Section 1.17 covers the details of percentage of United States recommended daily allowances (U. S. RDAs). These percentages differ from the RDAs put out by the Food and Nutrition Board in that these are averages covering a range of ages and are on the high side of the requirements of these age ranges. The section does state that the necessary items must be expressed in percentage of U. S. RDA. However, if any of the eight required nutrients are below two percent of the U. S. RDA, it is permissible to use an asterisk and to place a statement at the bottom of the tables saying "contains less than 2% of the U. S. RDAs (then list them) nutrients."

The nutrients must be listed on the information panel in the order published in the regulation.

Protein Efficiency Ratio

Section 1.17 defines the U. S. RDA of protein in relation to protein efficiency ratio (PER). The section states that protein with a PER less than 20 percent of the PER of casein cannot be used in terms of percentage of the U. S. RDA protein.

In addition to the listing of the mandatory eight nutrients that are required, once nutritional information is triggered, the listing of a large number of other nutrients (provided they are over two percent of the U. S. RDA) is allowed.

Section 1.17 covers claims of whether or not a food is a significant source of a nutrient. If the nutrient is present in a food at a level equal to or in excess of ten percent of the U. S. RDA in a serving, this claim can be made. However, a claim that a food is nutritionally superior to another food cannot be made unless the food contains at least ten percent more of the U. S. RDA claimed nutrient per serving.

This section further describes how to handle products with separately packaged ingredients or to which other ingredients are added by the user. It does give some options of how to label.

The regulations describe what must be done in the way of sampling and test procedures to ensure compliance with Section 1.17. They tell how this must be done, in addition to describing when a food with a label declaration of a vitamin, mineral or protein shall be deemed to be misbranded.

Substantial Part of Label

Section 1.17 is probably the most critical of all the regulations in that it affects a substantial part of the label. It is important to understand that complying with one section or one portion of a section may trigger the necessity of complying with another portion of this section. Or it may trigger compliance with an entirely different section. For instance, if fatty acids are mentioned on the label, that mention automatically triggers compliance with Section 1.18, which is entitled "Labeling of Foods in Relation to Fat, Fatty Acid and Cholesterol Content." Section 1.18 basically says that such a mention is allowed. However, any claim that the food is of value in preventing or treating heart or artery disease is not allowed because this is misleading to the consumer. If fatty acids and cholesterol are going to be mentioned, the section states exactly how it must be done. The section also describes the minimal fat content of the food on a dry weight basis or in an average serving that is necessary for the labeling to be acceptable.

If a cholesterol statement is on the information panel, the regulations allow the use of a phrase, put on the principal display panel of the label, stating where the cholesterol (fat) information appears. The regulations also limit the type size that is permissible in this area.

Another part, that leads into another area, is Part 100, which contains the nutritional quality guidelines for foods. It deals primarily with frozen heat-and-serve dinners. Anyone who wishes to sell a frozen product as a complete dinner must comply with the following. The product should contain at least the following three components:

(1) one or more sources of protein (a list of a variety of sources that can be used for the protein is included);

(2) one or more vegetables or vegetable mixtures other than potatoes, rice or a cereal-based product;

(3) the third item must be potatoes, rice or a cereal-based product other than bread or rolls (The regulations do allow the option of using another vegetable or vegetable mixture).

Minimal Level of Nutrients

Then comes the hooker—the three or more components that are used in the dinner (this would include any sauces, gravies or breading and so forth) must contain not less than the minimal level of nutrients described within this part. The regulations specify the minimum amounts of protein and various vitamins for each 100 kilocalories of the total components.

The regulations allow for the addition of nutrients, provided the nutrient level of whatever is added does not exceed 150 percent of the minimal level that is prescribed. They also specify that, when it is technologically practical, iodized salt shall be used, or iodine shall be present at a level which is equivalent to that which would be present if iodized salt were used in manufacture of the product. The regulations provide that, when it is technologically feasible, the product components and ingredients should be selected to have a one-to-one ratio of calcium-to-phosphorus. However, it is recognized that these cannot be mandatory.

Another hooker is that, if the product includes servings of foods which are not prescribed by Paragraph A (soup, bread, rolls, beverages or desserts), the nutrient contribution of those foods cannot be used in determining compliance with the nutrient levels of Part 100. Only the combination of the three mandatory components may be used. The regulations also state that, for purposes of labeling, an average serving shall be one frozen heat-and-serve dinner.

In order to prevent horsepower races, negative labeling is required. For instance, "The addition of ——— (to whatever product it may be) has been determined by the U. S. Government to be unnecessary and inappropriate and does not increase the dietary value of the food." I doubt that anyone would care to put that statement on his or her product. If nutrients are added to bring levels up to compliance with the nutritional guidelines, no claim or statement can be made on the label about it. It can be declared only in the ingredient statement.

Nutritional Labeling

Nutritional labeling, if one operates under the nutritional quality guidelines, is not necessary. It is only necessary to state on the label that the product provides nutrients in amounts appropriate for the class of food as determined by the United States Government. So,

basically, if one wishes to call a product a dinner, it is necessary to comply with the regulations. Otherwise, a term other than "dinner" would have to be used.

The compliance with the nutrient levels are the same as in Section 1.17 in that the same sampling procedures are necessary.

One of the problems that this creates in producing a product of this type is that it is not only necessary to determine the losses of the nutrients that may occur in the cooking of the product prior to freezing, but it is necessary also to determine the nutrient content of the raw materials being used. Furthermore, a producer must determine what the loss of nutrients may be in frozen storage and, also, what loss may occur in the products after they are heated in the home. It is necessary, I believe, to include a statement on the product that this is the nutrient content provided the directions for reheating are followed.

The frozen heat-and-serve dinner regulation also locks into Part 102, in that foods described as the main dish or dinner must be common or usual names. Thus, if one does not comply, there is another regulation form with which to deal.

Dietary Supplements

Part 80 is an interesting regulation on dietary supplements of vitamins and minerals; it covers definition, identity and label statements. This is the regulation that has been stayed by a court order and the one about which Congress is currently writing a law to allow vitamin supplements. To a large degree, it undercuts a great deal of authority on the part of the FDA in dealing with vitamins and mineral supplements in mixtures. It shows very definitely, I believe, the effects that a concerted amount of pressure can accomplish in Congress by a relatively small minority of the people. I will not discuss the details of Part 80 since it will undoubtedly be changed considerably once the law has been passed by Congress. It appears fairly definite that it will.

The final regulation that I will cover is that governing label statements concerning dietary properties of food that purports to be or is represented for special dietary purposes. This regulation, found in Part 125, defines special dietary use and covers such areas as special types of diets for allergies, lactation, pregnancy, convalescents, diabetes, overweight, etc. It also mentions foods that could be used or can be used as sole item of diet. Essentially, any type of food for which a

dietary claim is made is covered. A manufacturer must state in a conspicuous manner on the principal display panel what the food is to be used for. It must also cover very thoroughly the exclusion of claims that this food can prevent diseases, and other types of claims that are generally used by health food or organic food people relating to depletion of soil, or loss of nutrients in cooking, transportation and so forth.

Part 125 also describes label statements which relate to infant food and how the statements must be made. It also covers label statements relating to certain food used in control of body weight or dietary management of disease, in addition to label statements relating to hypoallergenic food and food as a means of regulating intake of sodium. The instructions in this regulation are quite explicit, and it behooves one to become very familiar with them because, in some cases, they are exceptions to other parts with which one may be more familiar.

APPENDIX

Formula and Label Compliance— A Checklist

Developing a new product in today's environment of concerns about safety and compliance with regulations is no easy task. The following checklist was put together to point out those elements which are critical in this process.

This checklist is intended primarily to cover product formula and labels. A key element in using this checklist is to document the information as much as possible. This includes written specifications, correspondence, analytical data, ingredient composition, food guarantees, contracts, nutrition data, safety studies and quality assurance procedures.

Formula Requirements

1. *Ingredients*
   (a) Verify that the ingredients are approved for use by the FDA and the United States Department of Agriculture (USDA) in the particular product at the particular level.
   (b) Verify the ability of suppliers to comply with FDA regulations and other requirements.
   (c) Establish appropriate specifications and test procedures for each ingredient.
   (d) Verify nomenclature to be used in the ingredient itemization.
   (e) Check to see if descriptive information is needed, for example, preservative, etc.
   (f) Verify that all components of an ingredient are known and cleared.
   (g) Verify that the processes, if any, used in the processing of ingredients are generally recognized as safe.
   (h) Verify that flavors are artificial or natural.
   (i) Verify that spices are used as such or used as a color.
   (j) Verify nutritional analysis, if necessary.

2. *Packaging*
   (a) Verify approval of all packaging material by the FDA and the USDA, particularly on food contact materials.
   (b) Determine environmental impact, if necessary.

(c) Verify compatability of package with state laws and regulations.

3. *Product*

(a) Conduct hazard analysis to determine if a hazard may exist and establish appropriate controls, for example, storage warnings, recipe, etc.

(b) Determine if nutritional claims will be used or if any other factors (such as adding nutrients that would trigger nutritional labeling) are present. If so:

(1) Determine nutrient content—of fresh product, of product at end of shelf life, and of product after preparation in the home including any added ingredients.

(2) Set up program statistically designed to monitor the product.

(3) If nutritional claims are to be made, ensure verification of the claims with data in files before marketing.

(4) Fill out information panel and verify correctness of the data.

(c) Establish quality assurance procedures.

Label Requirements

1. *Verify correctness of label*

(a) Name of product.

(b) Vignette—does it depict what the package contains and/or the end product?

(c) If components must be added, is this information prominently displayed?

(d) Is type size correct?

(e) Is net weight in proper place with sufficient color differential?

(f) Is the information panel where it belongs and is all the necessary information on it?

(g) Is the ingredient itemization correct in placement, order of predominance and the right nomenclature?

(h) Is nutrition information in correct format and verified?

(i) Verify recipes and other instructions.

(j) If warning statements (for example, refrigerate after opening) are necessary, are they in place and prominent? **[The End]**

Regulatory Survival Kit

By I. H. GOLDENFIELD

Mr. Goldenfield Is Regulatory Manager of Quality Assurance for Hunt-Wesson Foods, Inc.

THE RISK TO THE CONTINUED VIABILITY of existing products, or to the willingness of management to invest in new or modified products, is a function of surviving the regulatory obstacle course. The basic position of this presentation is that creative marketing and technical teams can maintain, conceive, develop and introduce food products that will not experience regulatory problems, if the creative team knows the regulatory limitations in advance. In many companies, the regulatory review function is not a clearly defined organizational entity, and its role very seldom starts at the concept stage of product development.

The purpose of this discussion is to suggest a method or system of ensuring that regulatory review and critique become an integral part of the food product protocol, which starts at the concept of the product and continues throughout the life of the product. The key elements of the regulatory problem prevention system are organization and communication. A regulatory affairs committee should be created to work with not only the marketing, research and development and legal departments, but with other staff areas that could affect the regulatory status of a product.

In this short presentation, I will try to suggest how the survival kit might work using a hypothetical example. Each company must develop and implement its own specialized system. The basic system presented stresses organization, pre-planning and ongoing communication as the keys to the reduced risk that this approach to product development offers.

I have provided a regulatory checklist (Chart I) that roughly simulates the life cycle of a food product. At each stage of the product life cycle, continuous regulatory review between the regulatory review team and the other interfacing departments is required.

In order to demonstrate how the survival kit works, let us use an example.

CHART I

Concept Stage

(1) *Product positioning:* What kind of product to meet an expected consumer response?

(2) *Advertising strategy:* What is the advertising message needed to sell the product?

Development Stage

(1) *Introduction:* The marketing team is the conductor, but the development follows two paths:
   (a) Marketing/Advertising;
   (b) Technical.

(2) *Marketing responsibility:*
   (a) Product name;
   (b) Labels and labeling;
   (c) Advertising;
   (d) Product quality.

(3) *Research responsibility:*
   (a) Product formulation;
   (b) Processing parameters;
   (c) Claims documentation;
   (d) Ingredient declaration;
   (e) Technical verification of all copy;
   (f) Prototype or protocept development.

Ongoing Consumer Product

(1) *Operations responsibility:*
   (a) Good manufacturing practice;
   (b) Emergency permit control;

(c) Recall procedures;

(d) Quality verification.

(2) *Marketing responsibility:*

(a) Label and labeling changes;

(b) Advertising changes.

(3) *Research responsibility:*

(a) Cost reduction;

(b) Product improvement.

Let us assume that the hypothetical product has been explored at the management level to the point where company development effort is authorized.

Marketing has decided on a product generally in the category of a "main dish souffle." At this point, the product could be a dairy, egg or fruit-flavored product whose form could be a dry mix, a frozen or a canned complete dish. It also has not been decided what type of name to use to go with "souffle":

(1) Cheddar Cheese Souffle;

(2) Cheese & Deviled Egg Souffle; or

(3) Fruit & Cheese Souffle.

With this background, let us partially follow the "Checklist for Compliance." Bear in mind that the system will work if constant communication between other staff areas is maintained. An appropriate vehicle could be a regulatory affairs committee. In each case, final review by the legal department is required before corporate decisions are finalized.

Pre-Development Stage

Marketing Responsibility: Marketing has decided, based on its market research data, to develop a line of souffle products containing cheese and/or eggs, with or without fruits, nuts and/or flavors. The preferred prototype name for this class of foods:

..... Souffle

The blank is to be filled in with the specific name of the product, such as:

(1) Cinnamon and Egg Souffle;

(2) Parmesan Cheese Souffle; or

(3) Nut and Fruit Egg Souffle.

Marketing has decided that these new products will be positioned as the main part of a lunch or dinner meal, with the primary ad strategy to be: "A Nutritious Complete Dish." The products should be basically "heat-and-serve" or "add one component," such as the egg.

Compliance Assessment

Existing Standards: This class of products is not a standardized food but the egg, cheese and possibly other components could be standardized, requiring limited latitude in formulation without affecting the product name.

Common or Usual Name: A petition to the Food and Drug Administration (FDA) for a common or usual name regulation could be utilized to define a class of products, such as souffles, that could force any potential competition to modify their product to meet the proposed new regulation. This procedure could, in effect, give the product a short lead time in the marketplace.

Restrictive Labeling Guidelines:

(A) *Egg to be Added:* If the product is designed to be made by adding eggs during home preparation, the product would be classified under Part 102.12, titled "Food Packaged for Use in the Preparation of 'Main Dishes' or 'Dinners.'" This regulation would require the name of the product to include three items as an integral part of the name every place on the label that the name is used:

(1) Name of product to be prepared—*"For a Cheese Souffle";*

(2) Common or usual name of components in the package in descending order—*"Souffle Base, Seasoning Mix";*

(3) Ingredients to be added to make prepared product—*"Add 3 Eggs."*

(B) *Canned Product—Ready to Eat:* The existing regulations controlling this product at present do not have special restrictions. The FDA proposal of June 14, 1975 included a proposed regulation for "Main Dish Products" under Part 102.20 which would require restrictive labeling similar to the "add egg" example.

(C) *Frozen Product—Ready to Eat:* Part 102 has a specific section (102.11) titled "Frozen 'Heat and Serve' Dinner" requiring special labeling similar to those examples noted above. This regulation, which is more restrictive, requires that the class of food "dinner" be reserved for a product having at least three components. This restriction, in effect, would require the product to fall into the category of the proposed regulation for "Main Dish Products."

The example of how a survival kit could work is only intended to demonstrate the concept. The use of this system not only has the potential for reducing regulatory risk, but has the added advantage of bringing facts to the product development system to permit better management decision making. **[The End]**

SPECIAL STUDIES MAY BE REQUIRED FOR INHALATION ANESTHETIC DRUGS

A proposal has been issued by the Food and Drug Administration (FDA) to require manufacturers of halogenated inhalation anesthetic drugs to conduct animal studies and submit reports to determine the carcinogenic and teratogenic potential of the drugs. Holders of approved new drug applications and future applicants would be required to conduct these studies. The FDA said that tests of nitrous oxide would also be required of the inhalation anesthetic drug sponsors since the approved labeling for these anesthetics recommends or suggests that they be used in combination with nitrous oxide.

The FDA's proposal was spurred by the concern of its Respiratory and Anesthetic Drugs Advisory Committee which concluded, nearly one year ago, that there is evidence indicating that halogenated inhalation anesthetic drugs may have carcinogenic and mutagenic potential. The Agency is not proposing to require mutagenicity studies because of an apparent lack of appropriate methods; however, the Commissioner of Food and Drugs is currently reviewing developing mutagenicity test procedures.

The design of test procedures used for the carcinogenicity and teratogenicity tests, according to the Advisory Committee, will be a crucial factor in providing interpretable data on the comparative risk of each product. The FDA proposes to hold a workshop to ensure that the studies are properly designed. Representatives from the National Cancer Institute, the National Institute for Occupational Safety and Health, anesthesiologists, the new drug application holders, and other interested persons would be invited to participate in the workshop.

Comments on the proposal may be filed until June 7, 1976.

CCH Food Drug Cosmetic Law Reporter, ¶ 45,344

AMERICA'S FIRST FOOD AND DRUG LAWS—POSTSCRIPT

The following two facsimiles are offered as a postscript to Wallace F. Janssen's article "America's First Food and Drug Laws," which appeared in the November, 1975 issue of the FOOD DRUG COSMETIC LAW JOURNAL. The prints are from the originals in the Library of Congress.

The first is a facsimile of the Massachusetts 1785 "Act Against Selling Unwholesome Provisions," which is generally regarded as the first comprehensive food adulteration law passed in the United States. A handwritten manuscript copy of the law, signed by Samuel Adams, is in the Commonwealth Library in Boston.

An Act againſt ſelling unwholeſome Proviſions.

WHEREAS ſome evilly diſpoſed perſons, from motives of avarice and filthy lucre, have been induced to ſell diſeaſed, corrupted, contagious or unwholeſome proviſions, to the great nuiſance of public health and peace:

Be it therefore enacted by the Senate and Houſe of Repreſentatives, in General Court aſſembled, and by the authority of the ſame, That if any perſon ſhall ſell any ſuch diſeaſed, corrupted, contagious or unwholeſome proviſions, whether for meat or drink, knowing the ſame without making it known to the buyer, and being thereof convicted before the Juſtices of the General Seſſions of the Peace, in the county where ſuch offence ſhall be committed, or the Juſtices of the Supreme Judicial Court, he ſhall be puniſhed by fine, impriſonment, ſtanding in the pillory, and binding to the good behaviour, or one or more of theſe puniſhments, to be inflicted according to the degree and aggravation of the offence.

[This act paſſed *March* 8, 1785.]

The second facsimile is of the 1649 Massachusetts "Act Respecting Chirurgions, Midwives and Physicians," passed also by New York in 1684.

FOR*asmuch as the Law of God allowes no man to impaire the Life, or Limbs of any Perſon, but in a judicial way*;

It is therefore Ordered, That no perſon or perſons whatſoever, imployed at any time about the bodyes of men, women or children, for preſervation of life or health; as Chirurgions, Midwives, Phyſitians or others, preſume to excerciſe, or put forth any act contrary to the known approved Rules of Art, in each Myſtery and occupation, nor excerciſe any force, violence or cruelty upon, or towards the body of any, whether young or old, (no not in the moſt difficult and deſperate caſes) without the advice and conſent of ſuch as are skillfull in the ſame Art, (if ſuch may be had) or at leaſt of ſome of the wiſeſt and graveſt then preſent, and conſent of the patient or patients if they be *mentis compotes*, much leſs contrary to ſuch advice and conſent; upon ſuch ſevere puniſhment as the nature of the fact may deſerve, which Law Ineverthelefs, is not intended to diſcourage any from all lawfull uſe of their skill, but rather to incourage and direct them in the right uſe thereof, and inhibit and reſtreine the preſumptuous arrogancy of ſuch as through preſidence of their own skill, or any other ſiniſter reſpects, dare boldly attempt to excerciſe any violence upon or towards the bodyes of young or old, one or other, to the prejudice or hazard of the life or limbe of man, woman or child. [*1649*]

PBBs—NEW THREAT TO HEALTH?

The accidental inclusion of between 500 to 1,000 pounds of hexabrominated biphenyl in animal feed resulted in the destruction of approximately 19,000 head of cattle, 4,000 hogs, one and one-half million chickens and over five million eggs, Food and Drug Administration (FDA) Commissioner Alexander Schmidt told the Senate Subcommittees on Health and Administrative Practice and Procedure on April 8. The incident took place in the Michigan area in 1973, Schmidt said, and by the end of 1975, lawsuits for damages arising from the incident totaled over half a billion dollars. Although a study by the Michigan Department of Public Health revealed no disease, symptom or laboratory finding that occurred among persons exposed to contaminated meat and dairy products, there might be long-term effects, Schmidt stated.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,612

BAN ON CHLOROFORM IN FOOD PACKAGING, DRUGS AND COSMETICS PROPOSED

The elimination of chloroform as an ingredient in human drugs, cosmetics and food packaging has been proposed by the Food and Drug Administration (FDA) in light of new evidence indicating that the substance causes cancer in test animals. Chloroform has long been used in small amounts in cough medicines, toothpastes and liniments, and as a solvent in making adhesives and resins in food packaging. The FDA cautioned that the animal experiments by no means prove that chloroform induces cancer in humans since the amount fed to the test animals greatly exceeds the amount to which any person could be exposed with present products. It was noted, however, that the benefits of chloroform are minimal and do not warrant any risk, however small. FDA Commissioner Alexander Schmidt encouraged industry to replace chloroform-containing products as soon as possible and advised that the FDA will not regard any removal from the market as a recall requiring the manufacturers to notify the FDA of such action.

The proposed ban on chloroform is based on a report presented to the FDA on March 1 by the National Cancer Institute. The report concluded that chloroform induces liver cancer in mice and renal tumors in male rats. Once adopted, new FDA regulations would prohibit the introduction into interstate commerce of any human drug or cosmetic containing chloroform after July 8, 1976. The proposal to prohibit the use of chloroform in food packaging would take effect after the same date. The closing date for comments on the proposals is May 10, 1976.

CCH Food Drug Cosmetic Law Reporter, ¶ 45,346, 45,347

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