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Food Drug Cosmetic Law JOURNAL

Additional Papers Presented at the 17th Annual Educational Conference of the Food and Drug Law Institute, Inc., and the Food and Drug Administration

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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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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

Seventeenth Annual Educational Conference of the FDLI and FDA. The following papers were presented at the 17th Annual Educational Conference of the Food and Drug Law Institute, Inc., and the Food and Drug Administration, which was held in Washington, D. C. on December 11th and 12th, 1973.

Heinz J. Eiermann, in "Cosmetic Ingredient Labeling," discusses the major labeling requirements provided for in the Fair Packaging and Labeling Act (October, 1973) and recent FDA proposals carried in the *Federal Register*. Mr. Eiermann is Acting Director of the Division of Cosmetics Technology, Bureau of Foods, FDA. This article begins on page 68.

Eugene I. Lambert in his article, "Carrot and Stick: Product Experience Reporting and Cosmetic Ingredient Labeling," discusses the advantages and disadvantages inherent in both voluntary CTFA regulations and mandatory FDA regulations. Mr. Lambert is the General Counsel of the Cosmetic, Toiletry and Fragrance Association. This article begins on page 78.

"Cosmetic Regulations," by *Sarah H. Newman*, promotes the necessity for comprehensive consumer protection in regard to cosmetics, emphasizing the importance of detailed ingredient labeling. Sarah Newman is a member of the Board of Directors, Consumer Federation of America. This article begins on page 83.

In an article beginning on page 88, *John A. Wenninger* urges the filing of cosmetic products experience reports for benefit to consumers and aid to industry in terms of marketing safer cosmetic products. Mr. Wenninger is Acting Director, Division of Cosmetics Technology, Bureau of Foods, Food and Drug Administration. His article is entitled "Voluntary Cosmetic Product Experience Reporting."

Certain aspects of ingredient labeling requirements, in the interest of consumers and government, but essentially from the industrial perspective, were discussed by *John W. Dickinson, Jr.*, Executive Assistant to the President, Personal Care Division, The Gillette Company. His article, "New Regulations for Cosmetic Product Labeling," begins on page 94.

"FDA Inspections—A New Approach," by *Joseph P. Hile*, describes the Hazard Analysis Critical Control Point Investigational Technique (HACCP), which is an FDA national inspection program. Mr. Hile is the Executive Director of Regional Operations, Food and Drug Administration. This article begins on page 101.

Richard J. Ronk, in his article "Food Additives as a System," stresses the need for a systematic approach to safety assessment in regard to consumer exposure to food additives. Mr. Ronk is Director, Division of Food and Color Additives, Bureau of Foods, FDA. This article begins on page 107.

Briefs Remarks on the Evolution of 21 CFR Section 80.1.—*Allan L. Forbes*, in his article "Brief Remarks on the Evolution of 21 CFR Section 80.1" reviews the inadequacy of public information in regard to vitamin and mineral preparations. Dr. Forbes is Deputy Director, Division of Nutrition, Bureau of Foods of the Food and Drug Administration. His paper was presented at the Food and Drug Law Institute Conference on "Vitamins—Food or Drug?" held at the Shoreham Hotel, Washington, D. C., on March 15, 1973. This article begins on page 111.

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Cosmetic Ingredient Labeling

By HEINZ J. EIERMANN

Mr. Eiermann Is Acting Director of the Division of Cosmetics Technology, Bureau of Foods, Food and Drug Administration.

SEVERAL WEEKS AGO, when we were still working on the final draft of the regulation on cosmetic ingredient labeling, Dr. Schaffner asked me to serve on this panel and discuss some of the questions that may be raised by industry after this regulation has been published. It goes without saying that I was delighted to have been offered the opportunity to participate in this conference.

The final order on cosmetic ingredient labeling, which was promulgated under the provisions of the Fair Packaging and Labeling Act, was published in the *Federal Register* on October 17, 1973 (38 F. R. 28912). It had its origin in a notice by the Commissioner of the Food and Drug Administration (FDA) in the *Federal Register* of August 11, 1972 (37 F. R. 16208) that provided guidelines for cosmetic ingredient labeling on a voluntary basis while Congress was considering legislation to this effect. When Congress did not enact ingredient labeling, Professor Joseph A. Page, Mr. Anthony L. Young, and the Consumer Federation of America, who on May 17, 1972 had originally submitted to the Agency a regulation on cosmetic ingredient labeling, requested that this petition be reactivated. At the same time FDA drafted its own proposal based on the voluntary guidelines. On February 7, 1973 the Agency published a notice of proposed rule making in the *Federal Register* (38 F. R. 3523) which contained both Page's and FDA's proposals.

The Agency received 291 comments in response to the proposals. Of these, 273 comments endorsed cosmetic ingredient labeling, with thirteen specifically endorsing the Commissioner's proposal, and eight endorsing the Page proposal. Ten comments opposed both proposals, and eight expressed neither endorsement nor opposition.

The issues raised in these comments and the Agency's responses are summarized in the preamble to the regulation. In the interest of time, I will not discuss the content of the preamble, and I will outline only the major provisions of the regulation. I will, instead, concentrate on the reactions we received after publication of this regulation. These questions and comments should be of general interest, and the arguments and answers should answer some of your own questions. Where appropriate, I shall at that time also refer to some of the statements in the preamble.

Major Labeling Requirements

The major labeling requirements are:

(1) The ingredients shall be listed in descending order of predominance.

(2) As far as fragrance or flavor ingredients are concerned, the individual ingredients need not be identified by name. The fragrance or flavor compound may be listed as fragrance or flavor. If an ingredient is a fragrance as well as a flavor, it must be listed as both fragrance and flavor unless it is identified by name.

(3) Ingredients which are accepted by the Food and Drug Administration as exempt from public disclosure because they involve trade secret issues need not be identified by name. The phrase "and other ingredients" may be used instead of a label declaration at the end of the ingredient statement.

(4) The ingredient declaration shall appear with such prominence and conspicuousness on an appropriate information panel that it is likely to be read and understood by ordinary individuals under normal conditions of purchase.

(5) Ingredients shall be identified either by the name established by the Commissioner or, in the absence of such a name, the name listed in one of the given sources. The primary source is the Cosmetic Toiletry Fragrance Association (CTFA) Cosmetic Ingredient Dictionary. It is followed by the United States

Pharmacopeia, the National Formulary, the Food Chemicals Codex, the United States Adopted Names, and the United States Pharmacopoeia (USP) Dictionary of Drug Names.

(6) If a cosmetic is also a drug, the active drug ingredients must be declared first as required under section 502(e) of the Federal Food, Drug, and Cosmetic Act.

(7) The effective dates are as follows: All cosmetic labeling ordered after March 31, 1974, and all cosmetics labeled after March 31, 1975, shall comply with this regulation.

Trade Secrets

When the cosmetic ingredient regulation was disclosed to representatives of the cosmetic industry at a panel discussion at the CTFA Scientific Seminar in Chicago, Illinois, most comments and questions centered on the handling of trade secret issues, and this subject continued to dominate the inquiries the Food and Drug Administration received afterwards from the industry. The suppliers of cosmetic raw materials and the manufacturers of the cosmetic products are concerned about the criteria the Agency may use to decide which ingredients may have trade secret status and would therefore be exempt from public disclosure. They have also been wondering how long it would take the Agency to decide on a request for such an exemption, what recourse they may have if an appeal to the Assistant Commissioner for Public Affairs were not decided in their favor, and what may happen to the label of a product while the ingredient declaration is in litigation because of a difference of opinion on the trade secret issue. The suppliers of raw materials, in particular, are worried about being forced to divulge to manufacturers of cosmetic products the quantitative formulae of the proprietary mixtures they are now selling as absorption bases, emulsifiers, or shampoo and speciality blends so that the cosmetic manufacturers can incorporate this information in their label declarations. These disclosures could, in many instances, result in considerable financial losses.

And then there is the general uneasiness over the interrelationship between the review of requests for confidentiality of the information disclosed to the Food and Drug Administration in response to the regulation on the voluntary registration of cosmetic ingredient and raw material statements, and the review of the same requests for exemption from label declaration of these ingredients in connection with the regulation on mandatory ingredient labeling.

Questions involving a trade secret issue are not easily answered. When is an ingredient a trade secret and when is it not? Each case has to be evaluated individually on its own merits. The scientific, technical and other information submitted in support of the request for confidentiality and similar information obtained through literature searches has to be carefully reviewed in order to judge whether or not an ingredient may be a bona fide trade secret and should therefore be held in confidence. In order for an ingredient to be recognized as a trade secret, it must be shown that it is unique, that it is important to the product, and that it is not known to competitors. Fragrance and flavor compounds, in general, meet these requirements. Proprietary mixtures of well-known ingredients that are offered as speciality blends to cosmetic manufacturers and are readily recognized or analyzed by cosmetic chemists do not qualify as trade secrets.

The tabulation of October 31, 1973 of the voluntary filing of cosmetic product ingredient and cosmetic raw material composition statements revealed that 702 of the 9,445 statements submitted to the Food and Drug Administration were marked confidential. The confidential statements represent only 7.4 percent of the total registration. The cosmetic ingredient statements marked confidential amount to 5.7 percent, and the confidential raw material composition statements encompass 17.2 percent.

Confidentiality and Mandatory Ingredient Labeling

A substantial number of these requests for confidentiality can be readily granted because they concern fragrance and flavor compounds which do not require declaration by name, and many of the remaining requests for confidentiality are expected to be withdrawn in coming weeks. A number of firms who demanded at the time they registered their formulations and raw materials with FDA that their statements be held in confidence did so with the intent of abandoning these requests when the regulation on mandatory ingredient labeling became effective. Several firms have approached us in recent weeks with this thought in mind and more inquiries of this nature are expected.

In view of industry's interest in re-examining the confidentiality status of earlier registered ingredient and raw material composition statements, the Division of Cosmetics Technology decided to send a letter to all firms that had filed confidential statements, suggesting that they re-evaluate their original requests for confidentiality made under the voluntary program and either confirm, revise or withdraw

such requests. They were at the same time given the opportunity to submit additional pertinent information in support of confidential requests.

In addition, the letter explains to these firms the interrelationship in regard to the confidentiality between the regulation for mandatory cosmetic ingredient labeling and the one for the voluntary filing of cosmetic ingredient and raw material composition statements. The letter points out that a request for confidentiality, if granted, will now not only exempt the ingredients from public disclosure by FDA under the proposed regulation on public information published May 5, 1972 (37 F. R. 9128) but will also exempt these ingredients from declaration on cosmetic labels under the provisions of the mandatory ingredient labeling regulation. You may recall that the regulation on public information was proposed by FDA pursuant to the provisions of Public Law 89-487, better known as the "Freedom of Information Act."

The Food and Drug Administration will review the replies to this letter as expeditiously as possible and will promptly inform the persons requesting confidentiality of the decision. Most requests for exemption from public disclosure should be answered within four to six weeks from the time a reply to the letter is received. After the initial backlog of reviews has been worked off, such decisions should be returned more quickly. Appeals to the Assistant Commissioner for Public Affairs should take approximately the same length of time for processing.

If an appeal to a decision on a confidentiality matter is rejected by the Assistant Commissioner, the firm may litigate the trade secret issue. Should the company decide to distribute the product during the period of litigation without declaration of the ingredient in question and use the phrase "and other ingredients" at the end of the ingredient declaration, and should the court rule against the firm, the merchandise in distribution would, of course, be misbranded.

As a paradox to the trade secret issue, one raw material manufacturer voiced concern that even if he were granted an exemption from public disclosure of an ingredient, he would still be at a commercial disadvantage because the cosmetic manufacturer may reject his material for reasons that he may not wish to state on his label "and other ingredients." He may feel that this could be a marketing liability. As a solution, the raw material manufacturer suggested that either CTFA or FDA give the secret ingredient a special name for the purpose of label declaration. On the surface, this looks like an in-

teresting idea; however, it would be contradictory both to the meaning of the term "trade secret," and to a meaningful declaration of ingredients.

Trade Secret Names

It was stated earlier that an ingredient may be considered a trade secret if it is unique, is important to the product and is not known to competitors. For the latter reason alone, the CTFA Nomenclature Committee could not establish a name for a trade secret ingredient because the manufacturer would have to reveal to the committee the material's exact chemical identity so the committee could determine whether or not two or more ingredients of one classification should be identified by a single "trade secret name" or should be given different names. If FDA assumed the responsibility of assigning the name, the trade secret status would still be in jeopardy if more than one raw material supplier used the ingredient and the same trade secret name were assigned to that ingredient. It would be tantamount to disclosure of the ingredient to competitors, and hence the ingredient would no longer be unique. On the other hand, if different trade secret names were assigned to one and the same ingredient because it is used by different raw material suppliers, FDA could be accused of consumer deception. The answer, apparently, lies in the judicious handling of requests for confidentiality of the ingredients the manufacturer considers to be trade secrets. Requests to this effect must be carefully scrutinized, and only valid trade secrets should be granted exemption from public disclosure.

Exemptions from Ingredient Labeling

Three questions that were raised deal with the subject of exemptions from ingredient labeling. Must samples that are distributed free of charge for promotional purposes declare their ingredients? What about conventional toilet soap products? Must the labels of products that are sold to the beauty trade and are intended for use in beauty shops bear the ingredient declaration? The answer to the first question is a definite "yes"; in the other instances, the answer is a qualified "no."

Free samples are not exempt from the provisions of the Fair Packaging and Labeling Act. The purpose of free samples is to persuade the consumer to purchase the product. For this reason the label should enable the consumer "to obtain accurate information as

to quantity of contents and should facilitate value comparisons." This is stated in the declaration of policy of the Act. The declaration of contents and of ingredients assist the consumer in this endeavor.

With regard to toilet soaps, ingredients would not have to be listed if the soap did not contain materials or bear labeling which would place the product into the drug or cosmetic categories. The Fair Packaging and Labeling Act gives the Food and Drug Administration the authority to promulgate regulations only for those consumer commodities which are covered by the Food, Drug, and Cosmetic Act (FD&C Act), and the definition of the term "cosmetic" of the FD&C Act specifically excludes soap.

In answer to the third question: Yes, cosmetics are exempted from label declaration of ingredients if they are distributed solely for use in beauty shops or cosmetic salons. However, if such products were used in the beauty shop and were also sold there to consumers for home use, or if they were customarily used by beauticians in the performance of services in the home, ingredient labeling would be mandatory. The Fair Packaging and Labeling Act defines a consumer commodity as any item which is

"customarily produced or distributed for sale through retail sales agencies . . . for consumption by individuals . . . for purposes of personal care or in the performance of services ordinarily rendered within the household . . ."

Several questions have come up since publication of the final order which concern the naming of cosmetic ingredients. One important question was:

"Can a cosmetic manufacturer rely completely on the CTFA Cosmetic Ingredient Dictionary and its supplements for selection of the proper label name of a cosmetic ingredient, particularly when a trade name needs to be identified?"

The answer is that the names listed in the Dictionary have been so far, and are expected to be in the future, the correct label names. Several trade names, however, are not correctly associated with their respective label names. Under the heading of Glyceryl Stearate, for example, the Dictionary lists the trade names of at least five proprietary raw materials that do not conform exactly to the Dictionary definition. These materials represent self-emulsifying grades of glyceryl monostearate, which means they must contain at least one additional ingredient, namely, a hydrophilic emulsifier, and this material must be declared on the label unless it has been exempt from public disclosure. Another example would be one of the proprietary raw materials identified as Ammonium Lauryl Sulfate. Most of the mate-

rial is ammonium lauryl sulfate; however, cosmetic chemists know that it consists partly of other active ingredients, and it contains also a fair share of water. There are many similar cases, particularly when it comes to raw materials which contain only 30 or 40 percent active ingredient and are diluted with water, alcohol or sodium chloride and sulfate.

Since it is the distributor of the cosmetic who is responsible for the ingredient declaration, he would be well-advised to double check the identity of a trade name ingredient before proceeding with the label declaration. If in doubt, he may even request an affidavit from the raw material supplier to this effect.

One person asked whether or not he could create his own label name for an ingredient which was not listed in one of the compendia mentioned in the regulation and whose chemical name was too long for the cosmetic label. The answer, obviously, is "no." He must either contact the CTFA Nomenclature Committee or submit a petition to FDA to request establishment of a specific name for his ingredient. He cannot coin his own name.

Order of Predominance

Another member of the cosmetic industry was concerned about the declaration of the reaction product of sodium hydroxide and stearic acid which was formed at the time the cosmetic was manufactured and which had a free fatty acid content of approximately 10 percent. The answer would be to declare either "Sodium Stearate" and "Stearic Acid," or "Sodium Hydroxide" and "Stearic Acid." Of course, in either case they would have to be declared in the proper order of predominance. One may apply the rule that an ingredient formed in situ may be declared either by its starting materials or by the reaction products. If, however, sodium stearate were added to the formulation, the label would have to read "Sodium Stearate."

A few individuals expressed concern about the listing of ingredients in the proper order of predominance. One person wanted to know whether predominance meant by volume or by weight in the case of a liquid cosmetic. Others wanted to know what would happen if an ingredient were listed out of order because additional material had to be added to the batch for a specific adjustment.

In answer to the first question, ingredients should be listed in relation to their predominance on a weight basis although there is something to be said for the argument that the volume relationship might be more meaningful in the case of a liquid product. As far as the second question is concerned, the answer can be found in the preamble of the ingredient labeling regulation. It is stated that ". . . the ingredient statement must list ingredients in order of decreasing predominance within the limits of accuracy permitted by good manufacturing practice." If the weight variation of an adjustment ingredient were minor, the mode, i.e., the most often occurring value, would be the preferred quantity value to be taken into account for the label declaration. On the other hand, if the weight variation was significant, the manufacturer would have to work with two sets of labels in order to comply with the regulation.

Declaration of Alcohol in Cosmetics

"How and when should alcohol be declared on a cosmetic product that is also a drug?" is another question that has been mentioned several times. The answer is quite straightforward: According to section 502(e) of the Federal Food, Drug, and Cosmetic Act, the label shall first declare "the established name and quantity of each active ingredient, including the quantity, kind and proportion of any alcohol. . ." This means alcohol will have to be listed quantitatively with the active ingredients before the cosmetic ingredients are declared. Furthermore, according to section 1.104(d)(2) of 21 CFR 1, the quantitative declaration must be expressed by weight if the product is a solid and by volume at 60° F if it is a liquid.

Location of Ingredient Declaration

Two questions related to the location of the ingredient declaration, particularly with regard to gift sets and kits which consist of two or more individual products or individually packaged mixing components.

The answers can be readily found in the preamble and the regulation itself. It is stated that the declaration of ingredients may be placed on any appropriate information panel; however, it must appear in such a way that it is likely to be seen, read and understood by ordinary individuals under normal conditions of purchase, which means under normal and customary conditions of display for retail.

Gift sets or kits which contain one or more products or individually packaged product components must, therefore, display the ingredient declarations of all products or components on an appropriate information panel of the set box or folding carton where it is readily seen at the time of purchase. Naturally, the bottom of the carton would not be considered appropriate for this purpose.

Appearance of the ingredient declaration on the carton will create a problem if the retailer breaks up the set and decides to sell the individual items separately. The manufacturer could, in this case, be accused of violating the ingredient regulation if the individual products did not display the ingredient declaration.

Letter Size in Ingredient Labeling

And finally, there was the lonely voice in the cosmetic universe who had problems in interpreting the meaning of the provision that the letters of the ingredient declaration shall be not less than 1/16 of an inch in height. He wondered whether this applied to "smaller-sized" letters, as for example, an "e" an "m" an "n" or an "o"; or it applied to "large-sized" letters such as a "b", an "s", an "f" or an "h." The answer to this problem can be found in section 1.202(h)(2) which reads:

"Letter heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter 'o' or its equivalent that shall meet the minimum standards."

The writing of a regulation is not an easy task. It is impossible to cover all contingencies. Although the preamble is an excellent device for explaining the requirements of a regulation in greater detail, particularly those which might be subject to misinterpretation or might be lacking specificity, questions always remain. I trust I have answered some of them. **[The End]**

Carrot and Stick: Product Experience Reporting and Cosmetic Ingredient Labeling

By EUGENE I. LAMBERT

Mr. Lambert Is the General Counsel for the Cosmetic, Toiletry and Fragrance Association.

THE FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS PUBLISHED on October 17, 1973, establishing a system for the voluntary filing of cosmetic product experience, and for the mandatory labeling of cosmetic ingredients constitute, from a legal standpoint, two radically different regulations. While they were joined together in publication, and in the formation of this panel discussion, it is important to keep them separated when analyzing them from a legal standpoint.

As you can see from the title of my paper, legally they represent two wholly different approaches to regulation. The product experience reporting regulation is designed to entice voluntary participation; the ingredient labeling regulation directs compliance in a mandatory fashion.

The product experience reporting regulation is the third leg of a total voluntary program petitioned by the Cosmetic, Toiletry and Fragrance Association (CTFA). The first two portions of the program—manufacturer establishment registration, and ingredient composition submissions—were issued as regulations in final form on April 11, 1972. Cosmetic product experience reporting was proposed in a petition submitted to FDA in July 1972, and published for comments, together

with a competing proposal on the Commissioner's own initiative, on November 2, 1972. Subsequent submissions by the CTFA, following the close of the comment period, suggested modifications in the Association's original proposal, modifications which constitute the essential framework of the final regulation.

CTFA's Voluntary Program

As with the other parts of the voluntary program, the Association's role is a crucial one. The Association initiated the voluntary program system. The petitions were developed by Association committees, circulated to Association members for comment, and ultimately reviewed and approved by the Association's Board of Directors.

The Association proposed the program. Each of the three legs of the program was based on public proposals submitted to FDA petitioning for the establishment of formal regulations. The Association petitions urged publication for public comment.

The Association has responded in each case both to suggestions made by the Commissioner when the petitions have been published for comment, and to comments from industry, consumer groups and other government agencies. In the case of the product experience reporting regulation, extensive Association comments were filed during the formal period for comments and were supplemented by additional suggestions, on the public record.

Finally, the Association has promoted the program. It has urged both members and non-members to participate. It has held educational seminars throughout the country, and highlighted the program at regular Association meetings. It has undertaken the reproduction and distribution of the forms for participation.

From a legal standpoint, this is a wholly voluntary program. This dictates two further legal considerations. *First*, the program must be one that the Association can promote within the limitations of the voluntary Association system, and thus must be one that creates incentives for participation. *Second*, those participating in the program are free to supply as much or as little data, within the limitations of the false statements provision of the Criminal Code, as they wish.

The Legal Uniqueness of the Program

Legally, this program is unique. Its uniqueness extends far beyond the voluntary nature of the program or its sponsorship by the Asso-

ciation. Its crucial uniqueness is its intent to cover an entire industry without regard for considerations of product composition, marketing history, or "newness." There is no product experience reporting system at all for foods. There is no comprehensive system for drugs; only drugs having approved new drug applications are covered by any reporting system. There is no comprehensive system proposed for devices; again only those specially regulated would be subject to reporting.

Voluntary Participation Seen as Key to Success

There are, necessarily, some legal and practical issues that remained unresolved in the final order of October 17. The meaning of an "audit" was one such issue. The scope of protection from public disclosure for individual product reports is another. The manner and adequacy of screening is a third. We believe that the inherent resolution of all three issues resides in the controlling legal fact that this is a program requiring voluntary and thus enticed rather than mandated participation. If the Association is, in good faith, to recommend participation to its members—if members are to be convinced that participation will not result in competitive disadvantage or in a dislocation of normal commercial operations—if non-members are to be convinced that participation is not some anticompetitive Association tool—each of these points must be resolved in a manner that promotes rather than frustrates voluntary participation. We believe that the key is indeed the one found in the public information proposal of May 5, 1972 in which FDA recognized that a more narrow disclosure policy is required where data and information can not be compelled and where FDA is dependent "upon good will of individuals and companies to receive this information. . . ." (37 F. R. 9131.)

The Cosmetic Ingredient Regulation

When one shifts the legal view from the product experience reporting regulation to the cosmetic ingredient regulation, an entirely different situation is at hand. This regulation is the result of a proposal both on the Commissioner's own initiative and as petitioned by a consumer group. It is issued pursuant to discretionary authority under Section 5(c)(3) of the Fair Packaging and Labeling Act (FPLA). As a regulation under that Act, its effect is limited to products of a "consumer commodity" that is in a "package." Cosmetics are, by definition, consumer commodities subject to the issuance of discretionary regulations by FDA. Such discretionary regulations apply,

however, only to cosmetics that are in a "package," *i.e.*, a container or wrapping in which the consumer commodity is enclosed for use in the delivery or display of that consumer commodity "to retail purchasers." This definition necessarily excludes samples and similar free goods. (No FPLA regulations, including the unique quantity declaration format requirements, are applicable to free goods; in my view, samples should not be confused with the combination purchase offer sometimes called "gift with purchase.")

In a similar fashion, the regulation does not apply to goods distributed other than at retail unless the goods are, with the knowledge of the manufacturer, ultimately consigned to retail distribution. Where goods not intended for individual retail distribution are shifted into retail channels, without the knowledge or consent of the original packer or distributor, we believe the Act imposes no liability on the nonconforming goods. Equally exempt from regulatory action are goods whose labels are changed after receipt in interstate commerce, as, for example, when a person breaks a gift set that is properly labeled in order to sell the individual items. This anomaly results from the fact that the FPLA prohibits only the improper introduction of goods into commerce and, unlike the FD&C Act, does not prohibit subsequent improper label alterations.

In comments and objections, the CTFA has dealt with a number of legal issues posed by the new regulation. In our view, the legislative history makes it clear that discretionary regulations, such as this one, are not to be issued on as broad a base as "cosmetics," but require a product line analysis to determine if the statutory criteria for their issuance is met. Despite the FDA assertions of broad authority, this is not an issue that has ever been tested or resolved in court.

The objections and request for a hearing filed by CTFA deal with two particulars aspects of the proposed regulation. The first is the requirement that the individual coloring materials be listed on the label of each cosmetic. The objections filed to this requirement challenge both the FDA's assumption that the statutory criteria necessary to impose this requirement have been met, and the Agency's failure to deal adequately with the trade secrets that are statutorily protected in this case. The second objection deals with the failure of the Agency to adequately recognize the forms of packaging used for small cosmetics, particularly the rack and compartment systems that are in widespread use, and that preclude the adoption of labeling, meeting any of the alternatives offered in the regulation.

ห้องสมุด กรมวิทยาศาสตร์

We believe it hardly meets consumers' desires for value comparisons if the only way such comparisons can be provided is at a substantial cost detriment to the consumer. The Agency's inability to relate value to the consumer to the cost increases inherent in its regulations appears particularly unfortunate where the regulations have a wholly economic base. Necessarily, this problem area is only exacerbated by the now foreseeable problems in the availability of labeling and packaging materials.

Voluntary Regulation vs. Mandatory Regulation

I do not wish to leave the impression that the CTFA has solely a negative position with respect to ingredient information. Numerous CTFA members have voluntarily embarked on a program of ingredient disclosure, and I am unaware of any company that will not cooperate with a consumer when particular problems of ingredient identification are posed. Certainly, the entire CTFA Ingredient Dictionary effort, which has now been recognized as the preferred nomenclature source, was undertaken and carried to completion with extraordinary speed and completeness in recognition of the need for suitable nomenclature for cosmetic ingredient labeling.

If the overall impact of two regulations makes anything clear, it is that carrots work better than sticks. A unique program that is worked out with full knowledge and understanding of economic consequences can be sold to industry and garner industry participation; conversely, a program that does not make adequate sense and has only economic justification should be equally objected to by industry who must bear the cost and by consumers who will bear the price.

[The End]

Cosmetic Regulations

By SARAH H. NEWMAN

Sarah Newman Is a Member of the Board of Directors, Consumer Federation of America.

CONSUMER CONCERN IN THE FIELD OF COSMETICS, as with all other products, rests on two of the basic rights of consumers—the right to safety, and the right to be informed. We feel the need has been amply demonstrated that the federal government should assume the responsibility for insuring that cosmetic products sold in the marketplace are safe, and that consumers be given the information that they need to make informed, rational choices and to protect themselves against unnecessary injuries.

Cosmetics, as we all know, are not a new phenomenon. They probably go back to Adam and Eve—surely to Eve. What *is* new is the heightened awareness of the possible damage from the multiple exposures to a mushrooming growth of new products. This has led to the increasing insistence by consumers for more adequate protection by the federal government.

Slow Progress in Consumer Protective Legislation

The cosmetic industry, for reasons that can be guessed at, has been able to resist coverage in consumer protective legislation quite successfully, and for quite some time. For many years, even when a cosmetic was known to be capable of causing harm or death, no federal agency had the power to stop its sale. Not until 1938 was the original Food and Drug Act of 1906 amended to include cosmetics, giving the Food and Drug Administration (FDA) the power to seize a cosmetic found to be injurious, falsely labeled or adulterated. However, this power gives no protection to the unknowing consumer who has already purchased the product and, unaware of the seizure by FDA, continues to use it. Moreover, soap (one of the most widely used cosmetics) was exempted and hair dyes containing

coal tar colors needed only to carry a warning on the label. Color additives were not covered until 1960, and that legislation's implementation was delayed for some years by industry opposition and litigation. An attempt to include cosmetics in the 1958 Delaney Amendment which bars additives shown to cause cancer in man or animals was defeated. The Federal Hazardous Substances Labeling Act of 1960 exempts cosmetics, so that no warning label is required even though a cosmetic product contains a known poison and may cause death if swallowed. Passage of the Fair Packaging and Labeling Act (FPLA) in 1966 granted to FDA the authority to establish ingredient labeling as necessary to prevent consumer deception or to facilitate value comparisons, but for cosmetics FDA required only that the label contain the name of the manufacturer, packer or distributor, and a declaration of net quantity.

Increase of Cosmetic Products

Meanwhile, the number and kinds of cosmetics increased fantastically. In 1914, cosmetic sales amounted to less than $40 million. According to a report in "Drug Topics" (9/22/71), American consumers in 1970 spent more than $7 billion on non-prescription cosmetics and toiletries, and more than $1 billion on cosmetic accessories. These products are not just for women, but for babies, children, teenagers and, increasingly, for men. The same survey reported that males will use almost one billion dollars worth of shaving preparations and accessories in a year, not mentioning the amount men spend on deodorants, hair preparations, lotions, etc. I am reminded of the day I testified on the Packaging and Labeling Bill in 1961. It was the same day that the cosmetic industry representatives were there, presenting their arguments for exemption from that legislation. Their contention was that they were not selling products—they were selling *hope*! I was amused by the look of incredulity on the faces of the male members of the committee when the witness went on to say that the industry was all set to extend this hope to men, and that they had indications that the market for cosmetics for men was just about ready to skyrocket. Well, they were right about the market, and the *hope* which they are selling to men is as totally divorced from any degree of efficacy as what they sell to women. While sales and products mushroomed, more and more American consumers had no information with which to protect themselves against unnecessary injury, or with which to make rational choices in the market place. The National Commission on

Product Safety reported that 60,000 people, mostly women, are injured by cosmetics every year severely enough to restrict activity for one day or to require medical attention. The National Clearing House for Poison Control centers reported that almost 3,000 small children were poisoned by swallowing cosmetics (not including soap and hair preparations) in 1970.

"Chamber of Horrors"

In an early thirties best-seller the public was warned that it could consider itself "one hundred million guinea pigs." Today, Congresswoman Sullivan warns that "as cosmetics are marketed today, the public serves as the cosmetic industry's two hundred million guinea pigs." The list of hazards has long been evident. From the blindness and death caused by eyelash dye, as in Ruth Lamb's "Chamber of Horrors" which helped get the 1938 amendments, to the more recent injuries from formaldehyde in nail polish, asbestos in talcum powder, chloroform in tooth paste, bacterial contamination (including pseudomonas) in hand lotions, mascara, baby powder, etc., photo-dermatitis from products containing salicylanilides or bithional, phenol in wrinkle removers, mercury poisoning from bleaching creams, allergic sensitization from antibiotics in deodorants, vulvitis and dermatitis from feminine hygiene sprays, overdose from hormones in creams—it is only the misery and anguish which has not been catalogued.

Fortunately, some of these hazards no longer exist. However, we do not know what new ones lie ahead. As a former assistant commissioner of FDA pointed out, "The problem today is not so much the products that are known to harm, but the cosmetics that are not known to be safe." The recent FDA regulations for mandatory ingredient labeling and the voluntary reporting system proposed by FDA will not take all the hazards out of cosmetics, nor will they result in removing all worthless products from the market. However, they will add to consumer protection.

Consumer Benefit

Consumers believe they have a right to know what is in the products they buy and use for two reasons: (a) to protect their health and (b) to protect their hard-earned incomes. Ingredient labeling will at least give those millions of consumers who suffer from

various allergies a chance to find out before they buy a cosmetic whether it contains the substances they must avoid (at least except for what is in fragrances and "trade secret" material). This should protect many from adverse reactions and should be helpful to physicians in treating cosmetic-produced reactions. It might also protect consumers from wasteful expenditure of money for things they cannot safely use. Hopefully, warnings will also be required on the labels which may help avoid some of the accidental mishaps, especially those involving children. However, I want to point out that soaps are still not included. Consumers might also find from reading the ingredients lists that there is sometimes practically no difference between a very expensive cosmetic and a relatively inexpensive similar product, thus being able to make a much more intelligent buying decision than is possible without ingredient information. Product claims that are unreasonable in relation to the ingredients in the product would also be less likely to appear. This might result in a saving of up to two billion dollars, which is what is estimated to be wasted yearly by American consumers in the purchase of useless or non-essential cosmetics.

Consumers feel it is time that industry began to change its old "knee-jerk" reaction to every attempt at regulation, and to recognize the need and, indeed, the value of some of the regulatory proposals. Some members of industry have taken that leap into the new era. Just this past summer one of the major supermarket chains in the Washington Metropolitan Area proudly announced its new policy with regard to ingredient labeling on 17 of its cosmetic products. It plans to list all ingredients, give warning cautions in large readable type, and restrict claims to statements of what the product actually does (no "puffery"). I was interested in the statement made by the president of the company when he characterized this new program as the most significant they had made because it "so directly impacted upon the health and safety of the community." He then went on to say, "We have found that a responsiveness to the needs of our community is enlightened selfishness—that, indeed, consumerism is good business."

Voluntary Product Experience Reporting

Now I would like to say a few words about the voluntary product experience reporting program proposed by FDA. What we have learned from previous voluntary self-regulation programs by industry

would not cause us to encourage more of them. In the first place, a voluntary program is *just that* and no member of industry has to cooperate. The experience so far, of the first two such programs in cosmetics, is a case in point. Even the members of the Cosmetic Toiletry and Fragrance Association (CTFA) have not all complied with these programs. Moreover, if a voluntary experience reporting program is adopted, the reports made to FDA might not be available to members of the public, and consumers would still be in the dark about what was going on. For example, if the complaints from consumers who used a certain areosol deodorant had been reported by the company to the FDA under the voluntary reporting program, the public might never have had access to the information. Only because the minutes of the meetings between FDA and the company were available under the Freedom of Information Act was the whole story made public. We also have some uncertainty about the screening procedure and its possible abuse, and some question about whether semi-annual filing is frequent enough. By and large consumers would prefer mandatory product experience reporting because all manufacturers would have to provide the information and public access to the information would be more easily obtainable.

Pre-Market Testing

While I have this captive audience please permit me to make a plea for pre-market testing. We know that many cosmetics are tested for safety before marketing, but there certainly are many which are not adequately tested. Surely those manufacturers who do test ought to support a requirement that *all* cosmetics be pre-tested by some accepted rational standards, if only to eliminate their unethical competitors, to say nothing of what it would do to build up consumer confidence in their products. Consumers know that no cosmetic will ever be 100% safe or worth every penny it costs for every person who buys and uses it. However, it is time to give consumers a break, and change the odds in our favor. If cosmetics is the "Great American Skin Game" let us change the rules so that all players have a fair chance. **[The End]**

Voluntary Cosmetic Product Experience Reporting

By JOHN A. WENNINGER

Mr. Wenninger Is Acting Deputy Director, Division of Cosmetics Technology, Office of Technology, Bureau of Foods, Food and Drug Administration.

IT IS CERTAINLY A PRIVILEGE for me to again serve on the cosmetic workshop panel at this Conference. Two earlier workshops at the meeting of this Conference in 1971 and 1972 dealt primarily with the subject of the voluntary cosmetic regulations which had been submitted to the Food and Drug Administration (FDA) as petitions by the Cosmetic, Toiletry and Fragrance Association, Inc. These regulations, as most of you know, have now all been published in final form.

Voluntary Cosmetic Regulations

The regulations make it possible for the cosmetic industry to report to FDA on a voluntary basis, the location of cosmetic manufacturing establishments, the ingredients in cosmetic formulations and information about adverse reactions that consumers report to industry about cosmetic products. My remarks today will be directed primarily to the third part of the voluntary program which calls for the "Voluntary Filing of Cosmetic Products Experiences." The final order for this regulation was published on October 17, 1973 (38 FR 28914-7).

The publication of the cosmetic experience reporting regulation completes the voluntary program which was initiated by the Cosmetic, Toiletry and Fragrance Association, Inc. in 1971. As a result of these regulations we have established a means of communicating

with the cosmetic industry that had never existed before. More important is the end result of our efforts, that the consumers can expect more information, more assurances of safety and more protection from injury than they have ever had before.

One of the problems in the past in regard to our responsibility for the safety of cosmetic products was that we simply could not efficiently obtain the information we needed to make judgments in the consumer's interest. It is a practical necessity that the Food and Drug Administration develop programs that are designed to achieve the greatest impact possible for the limited resources available. Our voluntary programs, especially the cosmetic experience reporting program, will help us direct resources more effectively in the future. These programs will not change how we regulate cosmetic products in the market place—only a change in the law would do that; it simply will provide us with reliable background information upon which we can make sound judgments in the public interest. It will be my purpose today to outline a few of the important aspects of the program and explain how we expect them to work in actual practice.

Cosmetic Product Experience Reports

The reporting requirements for the filing of cosmetic product experience reports are not complicated. Three forms are associated with reporting information on product experience. They are:

Form FD 2704 "Cosmetic Product Experience Report"

Form FD 2705 "Cosmetic Product Unusual Experience Report"

Form FD 2706 "Summary Report of Cosmetic Product Experience by Product Categories"

Each cosmetic firm that has had one or more adverse reactions reported to it on a cosmetic product is requested to file certain information on a semi-annual basis with FDA. The information to be reported for each cosmetic product will include the total number of adverse reactions and the total number of product units estimated to have been distributed to consumers during a given reporting period. The reporting form will request that the person making the report classify the alleged adverse reaction into one of several experience categories, such as: irritation, allergic reaction, infection, corrosive reaction and other. Classifying reported adverse reactions into these categories will, admittedly, be difficult in many instances. How-

ever, it has been our experience, in cases when a complainant has consulted a physician, that such classification is possible. Our instruction booklet for completing the forms will give guidance on this matter.

Following each reporting period, cosmetic firms are also requested to file a Form FD 2706 which is entitled: "Summary Report of Cosmetic Product Experience by Product Categories." This form permits each firm to summarize all of its product experiences by product categories. A total of 82 cosmetic product categories have been listed in the previous regulation which calls for voluntary filing of cosmetic product formulations. The summary form requests essentially three items of information for each product category that is marketed by a reporting firm: a three character alpha-numeric product category code, total number of reportable experiences for that product category, if any, and the estimated number of product units in that category distributed to consumers during a given reporting period. We want to emphasize that the person submitting the report need not list the products by brand name on the summary report but only the total number of product units in each product category estimated to have been distributed to consumers. This information will be required whether or not a firm has had a reportable experience for a product in that product category. We realize that this type of reporting may be an extra burden for industry. However, this is vital information for the Agency. Without such information we would be unable to establish a meaningful baseline on reportable experiences.

Benefit to Consumer

Let me give an example of how this information can be helpful to the consumer and in turn be helpful to industry in terms of marketing safer cosmetic products. Let us assume that the number of reportable experiences for a product category, for example, noncoloring shampoos, turn out to be x number per million units estimated to have been distributed to consumers. As a general rule, when a reportable experience rate on an individual brand name shampoo approaches or substantially exceeds the rate for the category we immediately know a review of complaints for that product is in order. Our review would include an evaluation of the type injury that was being reported, as well as the ingredients in the product. To carry out this review we would no doubt have to contact the manu-

facturer because the information provided on the form itself is not sufficiently detailed for a complete evaluation. The regulation has a provision which requests that firms who participate in the program retain all records pertaining to alleged cosmetic injuries for a period of three years. The regulation also provides for the possibility that FDA will request additional information from firms about the experiences being filed. However, we do not have to rely solely on this reporting program when we review the safety aspects of a specific product. We would be correlating the reports received under this program with those we receive directly from the consumer. After our review and evaluation I am confident that we would have all the necessary facts in regard to the magnitude of any problem and would be in a position to effectively take or recommend corrective action to benefit the consumer.

Consumer Product Unusual Experience Report

As I indicated earlier there is a third form associated with the program which is entitled "Cosmetic Product Unusual Experience Report." It is requested that this report be submitted immediately, or in any event within 15 days, for those reportable experiences which by kind, severity, or frequency of incidence differ significantly from the reporting firm's previous experience. The judgment of whether or not a given experience, or number of experiences, is in fact unusual would be one that each firm must face in regard to this program.

I would like to offer a few guidelines in regard to this matter. It is our opinion that any reportable experience with a cosmetic product that requires hospitalization would be unusual and should be reported as such. Any reportable experience involving a serious eye injury, (one which requires medical attention) when the product was used according to label directions, would also be an unusual experience and should be reported as such.

We would also expect that certain types of misuse of products, such as aerosol "sniffing deaths" and accidental injuries due to the flammability of a product, would also be reported using the unusual experience report. These reports would identify any unusual hazards associated with the use of cosmetic products and help the Agency institute corrective action on behalf of the consumer.

Definition of "Reportable Experience"

My discussion today would not be complete without reading the definition of "reportable experience" as defined in the regulation. It reads as follows:

"Reportable experience" means an experience involving any allergic reaction or other bodily injury, alleged to be the result of the use of a cosmetic product under the conditions of use prescribed in the labeling of the product, under such conditions of use as are customary or reasonably foreseeable for the product or under conditions of misuse, that has been reported to the manufacturer, packer, or distributor of the product by the affected person or any other person having factual knowledge of the incident other than an alleged experience which has been determined to be unfounded or spurious when evaluated by a filed screening procedure.

A filed screening procedure is defined as follows in the regulation:

"Filed screening procedure" means a procedure that is:

(1) On file with the Food and Drug Administration and subject to public inspection.

(2) Designed to determine that there is a reasonable basis for concluding that an alleged injury did not occur in conjunction with the use of the cosmetic product, and

(3) Which is subject, upon request by the Food and Drug Administration, to an audit conducted by the Food and Drug Administration at reasonable times, and where an audit is conducted such audit shows that the procedure is consistently being applied and that the procedure is not disregarding reportable information.

Screening Procedure

One of the more important aspects of the voluntary experience reporting program is the use of a "screening procedure." A "screening procedure" may be used to determine that there is in fact a reasonable basis for concluding that an alleged injury did not occur in conjunction with the use of a cosmetic product. We all agree that the use of a "screening procedure" to eliminate any alleged injury that is indeed unfounded, false or even fraudulent is desirable. However, we would not agree that an experience is not reportable or should be screened out simply because a consumer had not seen a physician. Many consumers simply discard a product to which they have had an adverse reaction rather than go through the expense of consulting a physician. Our review and evaluation of reportable experiences will take into consideration the nature of the injury as well as the number being reported.

In concluding my remarks today, I would like to urge the industry to cooperate in these very important programs. Today these programs are voluntary. For that reason there is understandable public doubt as to whether these programs will result in actions that really mean something to the consumer. I can tell you now that if they do not, the cosmetic industry will have abrogated a unique opportunity to shape its own contribution to consumer safety and product knowledge.

We feel the industry has made a good start, but I must emphasize it is only that—a start. There are many questions that must be faced in the coming year that will either allay or reinforce consumer doubts about these voluntary programs. These programs can be successful only if industry chooses to participate. **[The End]**

FDA PROPOSES TO IMPLEMENT SUPREME COURT DECISIONS ON NEW DRUGS

Opinions handed down by the United States Supreme Court on the authority of the Food and Drug Administration to implement the new drug provisions of the Federal Food, Drug, and Cosmetic Act have been incorporated into a proposed revision of the new drug regulations issued by the FDA. The amendments would include a definition of "well-organized and full factual analysis" required to accompany data submitted in support of a request for a hearing and would allow 30 days after the publication of a notice of opportunity for a hearing for filing a request for a hearing and 60 days for submitting the data and analysis.

Decisions in *Weinberger v. Hynson, Westcott & Dunning, Inc., Ciba Corp. v. Weinberger, USV Pharmaceutical Corp. v. Weinberger,* and *Weinberger v. Bentex Pharmaceuticals, Inc.,* established the principles that (1) the Commissioner of Food and Drugs has lawfully established the requirements of an adequate and well-controlled clinical investigation on the basis of which it can be determined if there is substantial evidence of effectiveness; (2) after a notice of opportunity for a hearing on a proposed withdrawal of approval, the applicant lawfully has the burden of coming forward with sufficient evidence to justify a hearing; (3) a hearing may lawfully be denied when evidence submitted in support of a request does not meet the standard of adequate and well-controlled clinical investigations; (4) the FDA has jurisdiction to decide with administrative finality the "new drug" and "grandfather" status of drugs; (5) the same quantity and quality of evidence is required to show that a drug is generally recognized as safe and effective as is required to show that it is, in fact, safe and effective; and (6) effectiveness requirements of the Act are applicable to all products related, similar, or identical to drugs for which a new drug application became effective prior to October 10, 1962.

CCH Food Drug Cosmetic Law Reporter

New Regulations for Cosmetic Product Labeling

By JOHN W. DICKINSON

Mr. Dickinson Is Executive Assistant to the President, Personal Care Division, the Gillette Company.

AS WE ALL ARE AWARE, the Food and Drug Administration (FDA) has issued final regulations for ingredient labeling. We also are awaiting final regulations for warning labels for aerosols, for feminine deodorant products, and a safety substantiation warning. The industry has filed comments to all of these proposed regulations. In addition, a new regulation covering hypoallergenics is expected—and it too may involve labeling.

Rather than to characterize my remarks as presenting a so-called industrial point of view, I prefer to speak of certain aspects of labeling requirements which deserve emphasis and explanation, in the interest of consumers and government, as well as industry. I would like to start with certain principles, by no means a complete statement of economics and government, but a few simplified statements which I think apply to my subject.

(1) First of all, cosmetic companies are in business to make money. The easiest way, in the long run the *only* way, is to satisfy their customers, the consumer.

(2) That means that consumers are going to get what they want, limited only by the technical ability to produce and deliver what the consumer wants to buy, and at a price that the consumer is willing to pay.

(3) The government's role is (or should be) to regulate without placing *unnecessary* restrictions or burdens on this business/consumer relationship. Such burdens, and I emphasize that I am speaking only of unnecessary or undue burdens, benefit no one and

ultimately are borne by everyone—not only stockholders, but also employees, taxpayers, and certainly consumers.

The relevance of these three points should be clear as I speak of the labeling regulations.

Disclosure of Cosmetic Ingredients on Product Labeling

First, let us discuss disclosure of cosmetic ingredients on product labeling. Understandably, marketers for the most part have been reluctant to interfere with packaging graphics (which are essential to product recognition and must be pleasing to the consumer) to accommodate something which may not truly be wanted by consumers, in the sense that it must be useful to be wanted. Except in rare instances, it remains highly questionable as to whether an individual can determine correctly which ingredients, if any, should be avoided. The argument also is made (and this forms the basis for claiming statutory authority under the Fair Packaging and Labeling Act) that ingredient labeling will facilitate value comparisons. As a marketing man, I can assure you that consumers make their value comparisons first on how the product performs against the individual's expectations and how well he or she likes the physical attributes (color, fragrance, texture, packaging and so on) before considering, if at all, the ingredients.

Nevertheless, the advocates of consumerism have convinced the consumer that he has a right to know the ingredients, aside from any question of usefulness. And so the cosmetic industry recognized there was no longer a question of whether the consumer wanted ingredient labeling or not, so even before the regulations were published, the industry set out to make it feasible.

Meaningful Ingredient Disclosures

Speaking of feasibility, if ingredient disclosures were to be meaningful, the ingredient names would have to be uniform and accurate from product to product. Cosmetic materials have been known variously by chemical names, trade names, and frequently by more than one name. The Cosmetic, Toiletry and Fragrance Association (CTFA) undertook the development of a comprehensive dictionary of cosmetic ingredient terms. This substantial reference work describes each material in detail and cross-references all of the names to the adopted names. This project started three or four years ago and required a tremendous amount of effort, not only by CTFA staff but by scientists from cosmetic companies, before the first edition could be published in spring of this year.

I emphasize this because, if the cosmetic industry had not recognized and been responsive to what the consumer was asking for (without being required to do so), there would not be a practical means of complying with the regulations today, certainly not in any way which could be meaningful. As proof of this, I would refer you to the results of a few well-meaning companies who attempted to label their ingredients a couple of years ago. Without criticizing the companies' intentions, they have listed the ingredients as a mixture of chemical names, generic or descriptive terms, or proprietary names. Sometimes the ingredient listings were incomplete and sometimes not consistent from product to product.

All that now is past and we face the task of compliance with final regulation. Despite comments about the originally proposed regulations filed by a variety of interested parties, the final regulation contains certain requirements which are extremely burdensome for some products or companies to meet, with little or no concurrent benefit to the consumer in whose name all this is being brought about. The degree to which the "problem" requirements are troublesome varies considerably from product to product within the broad spectrum of toiletries, cosmetics and fragrances covered by the regulation.

CTFA has filed a formal objection to Section 1.205(a) which requires specific designation of each color ingredient and has requested a formal hearing on the factual basis for this change from the original proposal. To begin with, the law requires that only listed color additives, accepted as safe for use by FDA, may be used; and there is a body of evidence substantiating their safety, including the fact that they are seldom the source of allergic reactions. Individual color ingredients are of no significance in attempting to make a value comparison. To the contrary, the choice of cosmetics is made invariably on the basis of the resulting color in use—a buying decision which considers skin tones, current fashion, compatibility with apparel, the particular occasion and so on. So there is really no medical or economic justification. On the other hand, unique and often subtle blends of color additives and diluents are among the most closely held of trade secrets, quite difficult to analyze chemically and providing considerable commercial and competitive value which would be jeopardized by disclosure.

While there is a provision for establishing trade secret status, it is impractical, unreasonable and certainly wasteful to require individual petitions for the 15,000 or so products which may validly claim such protection on the basis of color ingredients alone. Certainly 15,000

petitions cannot be prepared by industry and processed by FDA in time to meet the compliance dates, and it would be a kind of "Catch 22" to require listing on the labels while the petitions were pending. Finally, the provision for listing color ingredients compounds the problem which many products have in finding label space to list these in addition to the other ingredients.

The subject of label space brings me to Section 1.205(b), another provision to which CTFA has objected formally and requested a hearing. The general thrust of this section is to require that the ingredient information be readily discernible under normal conditions of purchase, which is perfectly reasonable so that the information can be seen and read by consumers. There *is* a minimum type-size requirement, but the latitude to list ingredients on any appropriate panel, or when space is limited, on a firmly affixed tag, tape or card, is welcomed.

However, the big problem arises out of the requirement that the ingredient declaration appear on or firmly affixed to the package. This simply fails to recognize the real world with respect to small cosmetics. Items such as lipstick, nail polish, and a multitude of facial makeup and eye products simply are too small and are customarily displayed in too close proximity to each other in special compartmented bins and displays for the required labeling methods to be practical. Every cosmetic product must undergo some change in packaging graphics, and incur substantial costs. However, for many small cosmetics to comply with the firmly affixed requirement would increase total product costs as much as 25 per cent—involving revised packaging, including possible use of boxes or cartons; or revised labeling, including protective covers for tags, tapes, etc.; and revising and replacing the semi-permanent trays and racks used for display or storage at retail. There is no consumer benefit to be derived in such costly measures compared with less expensive alternatives which should be permitted. Labeling the trays or racks with the required information or providing sheafs or pads of ingredient statements would provide entirely satisfactory and reasonable alternatives. Individual petitions to achieve such alternatives as provided by the regulation represent an impractical and unreasonable approach, since on a product-by-product basis there might be literally thousands of such legitimate requests for exemption.

Compliance dates also present a problem. The requirement that all cosmetic labeling ordered after March 31, 1974 and all cosmetic products labeled after March 31, 1975 be in compliance presents significant

problems for some products. This would include small-volume items where purchasing economics dictate procurement of quantities of labeling materials which will be used for a long time; products whose packaging is complex—some involving changes in bottle molds, etc.; and situations where new packaging or labeling machinery may be required. Actually, the magnitude of the graphics changes required for all cosmetics may present a general problem by swamping the available facilities and lengthening the lead times for all of the vendors involved in packaging graphics and materials. I shall speak further on the question of compliance dates in a moment.

I will comment only briefly on hypoallergenic cosmetics and feminine deodorant sprays. Whether or not any major new problems arise out of the final regulations, which have yet to be published, suffice it to say that the feminine sprays and possibly hypoallergenics will be required to make labeling changes *in addition* to the required labeling of cosmetic ingredients.

Regulations also are pending for label warnings to be required for aerosolized products and for a warning applicable to all cosmetic products "whose safety has not been established." Comments have been filed questioning the statutory authority for these, and I will make no attempt to go back over that territory. Practically, however, the general cosmetic safety warning shifts the burden of proof from FDA as it exists in the Food, Drug and Cosmetic Act (FD&C Act) to the marketer. Worse than that, it is so vague that every product is at the mercy of an arbitrary interpretation or determination. I doubt that anyone will ever attempt to market a product which adopts such a crepe label.

As to the warnings for aerosol cosmetics, many products already bear somewhat similar warnings voluntarily. The thrust of comments filed by industry is to the effect that specific warnings which are required should be applied quite selectively and only to products where the particular potential hazards are likely to exist. Warnings applied too generally are likely to generate among consumers a "ho-hum" bred of familiarity, and consequently a lack of heed to warnings generally. Further, the proposed language contained certain ambiguities and redundancies. In the interest of effective communication, hence consumer protection, the wording should be as clear and concise as possible. In any event, the final regulations can be expected to require all or most aerosol cosmetics to make changes in labeling, with com-

pliance dates undoubtedly different from ingredient labeling and possibly different from other labeling regulation compliance dates.

Consider the two label changes which aerosol products will be required to make for ingredient labeling and aerosol warnings and the three label changes required for feminine deodorant sprays and possibly for hypoallergenic aerosol cosmetics. If there is such an animal as a hypoallergenic feminine deodorant spray, it might have to make four label changes!

The cure for all of this is really quite simple—that is to delay the effective dates of ingredient labeling regulations and make them concurrent with the effective dates for all other pending regulations involving label changes. From a common date for compliance with all such regulations, there ought to be a period of nine months beyond which date labels ordered must be in compliance, and an additional twelve months after which products must be labeled in compliance.

Returning to the principles which I listed at the beginning: Consumers will be getting the cosmetic ingredient labeling which they have sought, and which has been made practical by industry's responsiveness in anticipating and solving the nomenclature problem before being required to do so. There apparently also will be the other labeling changes which I have described, and which have been sought by consumers or others on behalf of consumers. It is fair to say that industry efforts (sometimes misunderstood as recalcitrance) have been primarily to make sure that such labeling changes actually are wanted or needed by consumers and to be sure they are implemented as effectively as possible to meet their intended purpose. This is as important to consumers as it is to business, since the costs involved ultimately become part of the prices of the products. You may ask whether costs of this nature really are significant—and of course they *are*.

Changing a product's labeling involves redesign of the graphics by a professional designer and requires sketches, layouts and dummy packages. Where as much copy is added as will be necessary for ingredient labeling, many packages will have to be totally redesigned. Final art must be prepared and printing plates prepared; in some cases, new or modified bottle molds are required; and finally, the new labeling materials produced. The direct out-of-pocket costs for each product may run anywhere from $1,000 for the simplest change to $10,000 or more when the problem is more complex. This does not include indirect costs of marketing and management personnel as well as pur-

chasing, production planning and so on. Inevitably, any packaging change also results in a certain amount of obsolescence—which may run into additional hundreds or thousands of dollars for each product. Multiplied by perhaps 20,000 cosmetic products including sizes and shades, we may be talking about a one-time cost for artwork, plates, obsolescence and so on of a hundred million dollars, and possibly much more! Also, where ingredient labeling requires the *addition* of a new packaging component such as another label or a carton or a hang tag, the costs do not stop with artwork and plates. These costs, for added components, go on forever with *annual* costs undoubtedly running in the millions. Since ingredient labeling is wanted by the consumer and hopefully will be useful, then perhaps this is not too great a price to pay.

However, there is more—more that does *not* seem justified. If the present regulations are not modified, there will be additional large sums required to replace existing displays and bins for small cosmetics, many thousands of them costing several dollars apiece. Considering the satisfactory alternatives available, this would appear to be an unnecessary burden that the consumer did not bargain for and should not have to bear.

But that is only ingredient labeling. The same development and preparation steps and costs, as well as component obsolescence, are involved *each* time labeling changes are made. For many products we presently contemplate at least one more change and for some a third change—all of which could be accommodated just as well in a single labeling revision. So we now are piling additional large sums in the millions on the consumer.

As I have outlined, much of this cost can be avoided, without sacrificing a single bit of the consumer protection which is sought. Even if there were no concerns about ecology or inflation or the energy crisis, this constitutes a shameful economic waste.

I do not really believe that government wants this to happen any more than does business or the public. So I close with the fervent hope and expectation that the unnecessary imperfections in the labeling regulations will be corrected, including the adjustment of compliance dates for all of the labeling regulations so that they fall on the same date. **[The End]**

Food and Drug Administration Inspections— A New Approach

By JOSEPH P. HILE

Mr. Hile Is Executive Director of Regional Operations, Food and Drug Administration.

IF THERE IS ANY TRUTH in the old adage that "There is nothing new under the sun" then it is as applicable to Food and Drug Administration (FDA) inspections as it is to anything else. There are plenty of us still in FDA who were making inspections 20 and 30 years ago who are able to attest to this. Some of our inspections then were limited and designed to cover a large number of plants in a short time. Some were very extensive, taking a number of days for an in-depth look at the operation. Others, the more traditional, very carefully assessed the processes of the day, routinely evaluating raw material storage, manufacturing procedures, finished product storage and distribution practices. The type of inspection required was determined by the local office, and the use of the limited or very extensive coverage was mostly an *ad hoc* affair.

I hasten to add that I do not want to infer that there were no national programs or objectives. There were, but they did not prescribe the inspectional approach to be used throughout the country. This is truly the key to what we are doing differently now from what we were doing then, and this is why all of you in the canning industry are now particularly interested in the Hazard Analysis Critical Control Point Investigational Technique (HACCP).

Intensified Drug Inspection Program

The Agency undertook its first major national inspectional program in 1968. Those of you familiar with the drug industry will remember our Intensified Drug Inspection Program or the IDIP. Under this program, a nationally uniform intensive inspection approach was used to determine whether a firm was complying with the drug Good Manufacturing Practices (GMP's) or could be brought into compliance with them. Some plants got tired of seeing the FDA inspectors, but there were major overall improvements in the industry. At approximately the same time, a management consultant firm, which had studied the FDA field operations, recommended the planned national use of limited inspections. Part of the approach included a series of in-depth inspections to determine critical points or "key indicators" in the process. These "key indicators" could later be used to direct limited inspections.

FDA is currently using a variety of inspectional approaches as part of its national program. In some instances, the approach is still at the discretion of the local field manager. In others, like HACCP, the Agency is using a uniform approach nationwide to cover a given industry where a general set of problems has emerged and which requires FDA attention.

HACCP

"HACCP" is defined as the Hazard Analysis Critical Control Point Investigational Technique. "Critical" in this sense denotes a point where lack of control may present a potential danger to health in the product.

There is nothing mysterious about what FDA is doing in the HACCP program. We have combined several inspectional techniques with some new specialized training in a way we believe will best serve the needs of the Agency. The inspection technique can be simply divided into three parts: The first part consists of a traditional inspection of the plant covering the processing of the day together with a flow charting of the process and the identification of the critical control points in that process; The second part is to determine the extent of the firm's own quality control program covering these critical points; And the third part is to document the extent to which the firm is adhering to its own quality control program. The approach is designed to give FDA an insight into how the firm is running 365 days

a year, particularly when an inspector is not there. It is designed to rather precisely identify the potential problems associated with the product and it provides a clear definition of what needs to be done to correct objectionable conditions and procedures.

While we view the technique as an investigational tool, it is of significant value to the firms for their own use as well. It stimulates a firm to analyze its own process from a systems viewpoint. Plant management can identify potential trouble spots themselves and correct them, and they can verify the adequacy of their own internal quality control system, or develop one if none exists.

Procedure for HACCP Inspections

Obviously, HACCP inspections take a longer than usual time and require that many of the plant's management representatives and their records be available to our inspectors. For this reason, the Agency has started each inspection by inviting the plant management to participate in a pre-inspection conference. During this conference, the objectives of the program are discussed, and the persons and records that the FDA would like to have available are identified. The inspection itself is then initiated at a predetermined time. Although the unannounced inspection, with its obvious value to FDA, continues to be the primary approach used by the Agency, HACCP inspections do not require the surprise element to be effective. The inspection will be made by a single inspector or a team of two or more inspectors, depending upon the complexity and/or size of the plant.

Low Acid Canned Food Industry

As most of you know, the first application of the HACCP approach has been with the low acid canned food industry. Here the low acid canned food GMP's are the guide to the inspector. A total of 206 of these inspections have been made within the last year or so. In general, the inspections have been well received by the industry. A number of firms have commented directly that they have been greatly assisted by the inspection. Key control problems which they have missed through their own inspection program have been identified and corrected. Some firms had no real quality control program until after FDA had made its HACCP inspection and identified their crucial needs. Unfortunately, a small minority of firms have refused access to their records. As you know, they do not have to provide these

records, but it is a shame because such a refusal deprives the firm of an opportunity to have possible trouble spots identified by a fresh, objective observer.

The HACCP approach is proving most beneficial to FDA and ultimately to the consumer. It is much more important for FDA to prevent the production and distribution of violative products than to find them in channels of commerce and then have to precipitate their removal. The HACCP approach is allowing us to do this more effectively than ever before. A number of firms have actually ceased operations as a result of these inspections until major equipment improvements have been made and meaningful plant quality control procedures have been instittued.

Good Manufacturing Process Deficiencies

Application of the HACCP techniques to a wide variety of low acid canned food inspections has brought about the detection and correction of numerous good manufacturing process deficiencies. Some of the more significant deviations which have been noted in a number of establishments are as follows:

(1) Inadequate control over filling conditions and inadequate records of fill weights, drained weights and initial temperature, which are critical processing factors.

(2) Inaccurate mercury thermometers. Disagreement between recording thermometers and mercury thermometers. Use of recording thermometer as the criterion for process temperature instead of the mercury thermometer.

(3) Inadequate or unconventional venting techniques. Venting under water, and vent lines of excessive length. Use of globe valves for venting.

(4) Faulty retort construction. Inadequate bleeders, valves, and piping. No steam regulators. Improper location of bleeders and vents.

(5) Lack of scheduled processes, and lack of procedures for handling process deviations. Firms that have shortened process times, and firms unable to verify processes used.

(6) Inadequate records. Processing records lacking information regarding minimum initial temperature, mercury and record-

ing thermometer readings, actual process temperature, time steam on and venting parometers.

(7) Improper use of filling equipment creating conditions that could prevent proper heat penetration of the product.

(8) Inadequate steam supplies. Steam pressures observed varying or never reaching the recommended minimum pressure. Steam regulated by manual valves only. No heat distribution studies to determine adequacy of the pressures actually utilized.

(9) Lack of knowledge of critical control points of the process. Lack of clear understanding of process flow on a system basis.

(10) Lack of appropriate training of plant personnel in critical areas, such as retort operators. The use of personnel with language difficulties without adequate means to overcome these difficulties.

Firms—Significant Improvements

Where deviations were found by FDA, the firms have been formally notified of the deviations through the written notification by the inspector immediately following the inspection, by post inspection letter, or by inviting responsible firm personnel to meet with FDA personnel. As a result of these notifications, firms have made significant corrections. Improper and inadequate equipment has been replaced, and controls and record keeping have been initiated. The FDA has reviewed correction proposals made by these firms as an additional effort in aiding them in correcting deficiencies and establishing valid thermal processes. Retort operator schools have been scheduled at universities with the national canners association and FDA providing assistance. Needless to say, FDA is maintaining close contact with those firms that have not yet made all necessary corrections. Equally important to FDA is the fact that the Agency can better predict the quality of the plant's production in the future and evaluate the acceptability of products already on the market as a result of the HACCP approach.

Summary of HACCP Inspection

In closing let me summarize by saying that the HACCP inspectional approach is based upon a specialized inspection of an establishment's control of its processes, rather than a mere inspection of the operation of the processes on the day of the inspection. The HACCP inspectors analyze the production processes in a plant and identify

the points critical to the safety of the product. They determine the ability of the processors' quality control system. The inspectors review past performance of the plant by examining quality control records as well as by observing the plant in operation. Management is then informed of the critical points not being controlled. FDA then asks for a confirmation that deficiencies will be corrected.

It is important to remember that the HACCP is an inspection technique applicable to any one of FDA's different program areas, and is designed to be preventative in nature. Later this year we will begin inspection of plants packing selected frozen foods, and 50 additional inspectors will be trained in the HACCP procedures.

It is reasonable for one to believe that the national HACCP inspection approach will remain as a part of the FDA program. We are convinced it should stay because of its value to the consumer, this value arising as a result of FDA's ability to provide greater assurances that the consumer is receiving the highest quality products possible. FDA looks forward to the continued support of the regulated industry in helping make the HACCP work. **[The End]**

COURT REFUSES TO RULE THAT "ME-TOO" DRUGS ARE NOT NEW DRUGS

Determinations of whether or not a drug is a new drug are to be made initially by the Food and Drug Administration, and its procedure of allowing an abbreviated new drug application for "me-too" drugs does not affect the new drug status of these drugs, according to the U. S. District Court. A pharmaceutical association sought a judicial determination that "me-too" drugs the FDA has evaluated as effective for use under specified conditions and labeling are not new drugs. The court said any finding that drugs are new or old depends upon whether they are generally recognized by qualified experts as safe and effective for their intended uses, not upon their actual safety or effectiveness. Such a finding must be made by the FDA for each drug before it ceases to require a new drug application. Accordingly, the complaint of the pharmaceutical association was dismissed.

The National Ethical Pharmaceutical Association and Pharmaceutical Associates, Inc. v. Weinberger, et al., DC S. C., ¶ 41,058
CCH Food Drug Cosmetic Law Reporter

Food Additives As A System

By RICHARD J. RONK

Mr. Ronk Is Director, Division of Food and Color Additives, Bureau of Foods, Food and Drug Administration.

ONE OF THE THINGS that management, in both corporate and government life, is enthusiastic about, is exposing an operation to in-depth analysis—systems analysis. It can be a rather frustrating experience for a manager to have to justify, not only superficial aspects of, for example, the flow of paper work through his operation, but also to have to justify the basic assumptions by which his business operates. Does the Toonerville Trolley and Aircharter Company contribute to Interstellar Airlines or is it a drain of resources? Does the food additives program of the Food and Drug Administration (FDA) assure the safety of function ingredients added to foods?

Systematic Approach to Safety Assessments

Since all of us have been somewhat schooled in the techniques of the systems analyst, we become uneasy and think the worst. We find it appears that our operations lack system. This is really what the Generally Recognized as Safe (GRAS) list review and GRAS affirmation petitions and the other initiatives of the food additives program entail. In FDA's view, the public's concern about food additives flows not from a finding of hazards, but rather from an uneasiness that we all feel when we are confronted with what appears to be a lack of a systematic approach to safety assessments. I have no criticism in regard to the statute. However, as managers, let us face facts! It is extremely difficult to operate a system which requires the positive

listing of ingredients added to foods, and yet allows a food firm to decide, on its own initiative, that an unlisted item is generally recognized as safe (GRAS) and need not be listed. Thus the GRAS affirmation petition was born. It brings system to this kind of GRAS judgment. It also implies that the GRAS list will become inclusive. How inclusive will depend on how necessary it is to list items such as nonfat dry milk and butter, as opposed to listing whey solids and hydrolyzed vegetable protein which are a little further from what one finds included in a reasonable definition of food. When the GRAS list becomes as inclusive as it can practically be, then perhaps it will make a more precise definition of food possible. Thus essentially there will be a positive listing of function ingredients added to food. Along these lines, we have some continuing projects and some new projects which will be of interest to you.

Review of Nonflavor Ingredients

The safety review of the GRAS list is showing progress. On July 26, 1973 a series of proposals were published in the *Federal Register* which explains the review procedures, and also breaks some new ground. For example, one proposal made an attempt at defining functional effects and commodity categories. The following numbers give some sketchy indication of progress toward our goal of completing the review of the nonflavor ingredients in 1974.

Total GRAS substances published	592
GRAS substances unpublished	83
Total GRAS substances under review	675
Less GRAS flavors under separate review	252
Total GRAS substances (less flavors)	423

Status of Scientific Literature Reviews (nonflavor)

62 Reviews on hand covering	212 substances
58 Reviews in preparation covering	128 substances
Reviews in contract stages covering	83 substances
Total GRAS substances in Scientific Literature Reviews	423

Status of Evaluation by the Federated American Societies for Experimental Biology (FASEB)

19 Review evaluations completed	25 substances
43 Review evaluations in process covering	187 substances
Total 62 Review evaluations covering	212 substances

Scientific Literature Reviews (Flavors)

Reviews in preparation covering	276 substances
Reviews under negotiations	622 substances
Balance to be arranged	642 substances
	1540

No flavor evaluations have been scheduled as yet.

The FASEB expert committee will complete the basic evaluation of 212 substances by March and the reports and *Federal Register* proposals should appear by June 1974.

Estimation of Consumer Exposure to Food Additives

We are working hard this year to find better ways to estimate consumer exposure to food additives. To be useful, these exposures must relate to sex and age, and perhaps to cultural food consumption patterns. The National Academy of Science/National Research Council industry use survey of 1970 which blended with United States Department of Agriculture/Market Research Corporation of America (USDA/MRCA) data was our first attempt at a more sophisticated estimation of exposure. This year we are contracting with the MRCA to provide a Food Frequency Consumption Data Bank. This bank will yield current information about the public's 1974 appetites. We will again go to the Academy, asking them this year to update, refine and in some cases milk, the 1970 industry use survey for new information. In late 1974 and 1975, a new industry use survey will concentrate on direct, regulated food additives. This of course is preliminary to full scale safety review of regulated additives which would begin in 1975.

We are not neglecting our principal food additive client, indirect packaging materials. A new draft of the "Guidelines for Chemistry and Technology Requirements of Food Additive Petitions" is in the

final stages of review and will be published ahead of schedule in February of 1974. A safety review of regulated indirect food additives is scheduled for 1976. The plan for this review will be developed later this fiscal year. I can only urge those of you who may be affected to get in touch with us and let us have your ideas about how we should structure this review. This invitation holds for private as well as corporate individuals.

Toxicological Evaluation Program

There is another area of FDA's food additive work which also is undergoing a systems overhaul, our toxicological evaluation program. A new system for evaluating the potential for genetic damage from ingested chemicals is under way. Previous methodology such as the host mediated assay, cytogenetics, and dominant lethality, have been found to be unreliable for a realistic appraisal of genetic damage. Thus the need for a new system. The new system is a three-tiered approach to mutagen testing. The first tier is a rapid prescreen which identifies all presumptive or suspect mutagens. The second tier employs a combination of more sophisticated tests to determine whether the suspect chemical is mutagenic in animals. Finally, an attempt is made to quantify associated risk to human health at realistic levels of exposure to the mutagen. The feasibility of toxicological guidelines will also be explored again this year.

If one is to have a safety evaluation system, the basis of that evaluation must be part of the public record. If there are no published guidelines and evaluation is strictly a case-by-case process, the system tends to become arbitrary and dependent upon individual rather than agency decisions. Thus, we will make an effort in 1974 to publish such guidelines.

This is a very brief summary of a few of the important projects that are part of the present and future food additive program plans. I hope that the initiatives that blossomed over the last three years will bear the fruits we expect this year and in 1974 and 1975. Success however will be measured, not in terms of how pleased FDA and industry may be with the way we handle our joint responsibility of assuring the safety of additives; rather success will be measured in the degree the American public feels that our food additive safety evaluation system works.

[The End]

Brief Remarks on the Evolution of 21 CFR Section 80.1

By ALLAN L. FORBES

Dr. Forbes Is Deputy Director, Division of Nutrition, Bureau of Foods of the Food and Drug Administration. His Paper Was Presented at the Food and Drug Law Institute Conference on "Vitamins—Food or Drug?" Held at the Shoreham Hotel, Washington, D. C., on March 15, 1973.

AT THIS POINT, I do not wish to review the details of the content of Section 80.1 on dietary supplements of vitamins and minerals as published in the *Federal Register* on January 19. I simply want to emphasize a few key points which underlie the evolution of Section 80.1. Shortly after World War II, the explosion in vitamin and mineral preparations really got under way. Products containing every conceivable number and quantity of vitamins and minerals were promoted and became readily available to everyone. In addition, vitamins and other nutrients were combined with all sorts of drugs such as thyroxin, belladonna alkaloids, digitalis, and so on. Then, along came a number of substances claimed to have special nutritional qualities without substantive information to back up the claims, such as the bioflavinoids. The result of all this was chaos in the marketplace, widespread abuse of sound nutrition principles and the widespread practice of nutrition nonsense, which persist to this day. We, as a nation, are not only like most other peoples around the world in being nutritionally ignorant or indifferent, but the information we do have is often mixed up to a worse degree than anywhere else.

By the late 1950's, the nutrition community in the nation began to get pretty exercised by the chaos, confusion and malpractice. One of the first groups to try to bring some order out of this situation was the Council on Foods and Nutrition of the American Medical Association, who published, in January, 1959, their statement entitled "Vitamin Preparations as Dietary Supplements and as Therapeutic Agents." This, plus the 1958 version of the Recommended Daily Dietry Allowances of the Food and Nutrition Board at the National Academy of

Sciences/National Research Council, was the granddaddy of Section 80.1. At the same time, the Food and Drug Administration also became concerned about the same situation. Hence, the Commissioner published in June, 1962, a notice of proposed rule making which would concern dietary supplements. This led to objections and requests for a public hearing. A final order was published and immediately stayed in December, 1966. The hearing was authorized at the same time and took place between May, 1968 and May, 1970. The Hearing Examiner's Report became available in January, 1971, and the end result of an extremely intense review of all of this history and the public hearing was Section 80.1 as published on January 19.

Basic Principles to Govern Final Regulations

Not being a lawyer, I do not have command of the proper legal terminology, but I can say that out of this history, and the public hearing in particular, came a crystal clear sense of the proper course of action, or, if you like, a set of basic principles that should govern development of the final regulation for dietary supplements. These were, and remain, as follows:

(1) Assurance to the public that supplements are based on modern nutrition knowledge, using the Recommended Dietary Allowances of the Food and Nutrition Board as the basic guide.

(2) Protection of the public's health against supplements containing potentially toxic quantities of individual nutrients and against supplements containing insignificant quantities of individual nutrients.

(3) Protection of the public against gross nutrient imbalances and omissions in products marketed as multicomponent supplements.

One can, of course, add to these the obvious matter of protection against untruthful or misleading claims, and the needs for a uniform labeling system and expiration dating.

A last point I would like to make is the need for keeping dietary supplements of vitamins and minerals in perspective. If what I hear and read reflects current general thinking, this perspective keeps getting lost. A dietary supplement is exactly what the name says it is. It is a food containing reasonable quantities of essential nutrients ingested whenever the adequacy of the daily diet is deficient or in doubt to insure a total daily intake of these nutrients in amounts corresponding to what is contained in a normal, well-balanced diet. They are not intended to be large additions to a well-balanced diet. They are not intended for the specific treatment or amelioration of the symptoms of disease. Vitamins or minerals used for the latter purposes are drugs, be they over-the-counter or on prescription. **[The End]**

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