

1-1-1974

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Recommended Citation

Ronald G. Fischer, *Cosmetic Labeling: The FDA's Response to Consumer Needs*, 14 SANTA CLARA LAWYER 542 (1974).
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COSMETIC LABELING: THE FDA'S RESPONSE TO CONSUMER NEEDS

Ronald G. Fischer*

INTRODUCTION

For a long time consumers have been concerned about the ingredients in the cosmetics they buy. With the expanding use of cosmetics by both men and women, there has emerged a compelling need for information which will enable consumers to compare and evaluate the countless cosmetic products on the American market and to protect themselves from deleterious effects of certain cosmetic ingredients. Consumers, of course, want to know which brand or type of cosmetic within their price range will best satisfy their needs. But more importantly, each individual consumer must also know what substances are in each cosmetic in order to avoid those ingredients to which he may have an allergic reaction. In response to these needs there has been considerable emphasis by consumer groups in recent years on requiring ingredient labeling of cosmetics.

The Federal Food, Drug and Cosmetic Act of 1938 (FDCA) includes cosmetics within its coverage¹ but nowhere requires ingredient labeling of cosmetic products. Some congressional interest in amending the Food, Drug and Cosmetic Act has emerged at various times, but no bills have moved beyond the committee stage. An industry group, the Cosmetic, Toiletry, and Fragrance Association,² has helped to implement *voluntary* ingredient disclosure but these disclosures are made only to the Food and Drug Administration (FDA), the regulatory authority

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1. 21 U.S.C. §§ 361-63 (1970) [hereinafter cited as FDCA].

2. The Cosmetic, Toiletry, and Fragrance Association is a trade organization with a membership including approximately two-hundred companies which produce more than eighty-five per cent of the United States' total production. See 36 Fed. Reg. 16934 (1971).

charged with the responsibility for enforcement of the FDCA, and not to the general public.³

Since the FDCA itself requires no ingredient labeling of cosmetics, the Food and Drug Administration has utilized the Fair Packaging and Labeling Act⁴ as the enabling legislation to promulgate a regulation mandating ingredient labeling on cosmetics after March 31, 1975. This article will outline these two acts which bear on cosmetic labeling. It will trace the legislative failure to respond to consumer demands for better cosmetic information and the FDA's subsequent use of voluntary ingredient labeling regulations promulgated under the Food, Drug and Cosmetic Act and later mandatory labeling through regulations promulgated under the Fair Packaging and Labeling Act. It is only with these very recent FDA regulations that consumers have won meaningful and useful disclosure of cosmetic ingredients.

THE FOOD, DRUG AND COSMETIC ACT

Enacted in 1938, the Federal Food, Drug and Cosmetic Act⁵ constitutes the basic consumer law in the area of cosmetic regulation. The term cosmetic is broadly defined to include any article which is applied to the human body or any part thereof by means of rubbing, pouring, sprinkling or spraying, with the intent to cleanse, beautify, promote attractiveness or otherwise alter the appearance of part or all of the body.⁶ The FDCA definition also includes any component article of a cosmetic, but specifically excludes soap from the definition.⁷

A central concern of the Act is to avoid dangerous adulteration and misbranding of cosmetics. Under the Act, a cosmetic

3. Regulations regarding voluntary ingredient disclosures provide that such information may be passed on to the public on request except that any information "constituting a trade secret or other privileged and confidential commercial information exempt from disclosure to the public" must be designated confidential by the party submitting it and must be accompanied by a specification of the grounds justifying its confidentiality. The FDA may then determine whether the information is indeed confidential or not. 21 C.F.R. § 172.9 (1973). Under FDA proposed rules on Public Information (37 Fed. Reg. 9132-33 (1972)), the asserted confidentiality of voluntarily submitted material will be determined at the time of submission, and if the information is found not to qualify as confidential the party submitting it will have an opportunity to withdraw it to avoid public disclosure.

4. 15 U.S.C. § 1451 *et seq.* (1970) [hereinafter cited as FPLA].

5. 21 U.S.C. § 301 *et seq.* (1970).

6. *Id.* § 321(i)(1), (2). Categories of cosmetic products are: baby products, bath preparations, eye make-up preparations, fragrance preparations, hair preparations, hair coloring preparations, make-up preparations, manicuring preparations, oral hygiene products, personal cleanliness, shaving preparations, skin care preparations, and suntan and sunscreen preparations. 21 C.F.R. § 172.5 (c) (1973).

7. 21 U.S.C. § 321(i)(2) (1970).

is considered adulterated if it contains a poisonous or deleterious substance,⁸ or if it has been contaminated in preparation or packaging.⁹

Misbranding of cosmetics may occur in any of the following circumstances: 1) the labeling is false or misleading in any particular; 2) the label does not bear the name and business address of either the manufacturer, packer or distributor; 3) the label does not present an accurate statement of the quantity of the contents by weight, measure or numerical count; 4) the required explanation of quantity of contents and name of manufacturer is not conspicuously printed; 5) the container is itself misleading; 6) the product is a color additive and the labeling does not conform with the packaging and labeling requirements applicable to color additives; or, 7) the packaging and labeling violates any of the regulations issued pursuant to the Poison Prevention Packaging Act of 1970.¹⁰

Despite its obvious relevance to avoiding adulteration and misbranding, ingredient labeling is not required by the FDCA.¹¹ This absence of a labeling provision may be contrasted with the FDCA's requirement that the labeling on the container of any food product (except those with standard recipes) must disclose in clear terminology the ingredients used.¹² In addition to the information required on cosmetics labels, food labels must bear the common and usual name of the food product and, if two or more ingredients are combined, the common name of each. If any of the additional ingredients are spices, flavors or colorings, these may be designated as such without further specification.¹³

With regard to drugs,¹⁴ the third commodity group regulated by the Food, Drug and Cosmetic Act, the Act requires that the established name and quantity of each active ingredient in drugs

8. Cosmetics are among the items controlled by the Poison Prevention Packaging Act of 1970, 15 U.S.C. § 1471 *et seq.* (1970).

9. 21 U.S.C. § 361 (1970) ("poisonous", "deleterious" and "contaminated" are *not* defined by the FDCA).

10. *Id.* § 362; *see also* Poison Prevention Packaging Act of 1970, 15 U.S.C. § 1471 *et seq.* (1970).

11. 21 U.S.C. § 362 (1970).

12. *Id.* § 343.

13. *Id.*

14. *Id.* § 321(g)(1) defines "drug" as:

(a) Articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in men or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of men or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories.

fabricated from two or more ingredients be disclosed on the label. Furthermore, the label must state the quantity, kind and proportion of alcohol or any of eighteen other named ingredients, whether active or inactive.¹⁵

Thus, of the three basic commodity groups regulated by the Food, Drug and Cosmetic Act *only* cosmetic labels need not include a list of ingredients. A review of the FDCA's legislative history reveals no responsiveness on the part of the Congress to efforts to include an ingredient labeling requirement for the cosmetics industry similar to those imposed upon the food and drug industry.

Efforts to Include Cosmetic Ingredient Labeling Requirements Within the FDCA

In 1933, the first bill to revise the existing Federal Food and Drug Act of 1906 was introduced into the Senate. Even at this early date efforts were being made to require that private formula drugs, that is, those which were not included in a recognized industry listing of drugs and drug formulae, bear the name, quantity and proportion of each medicinal or physiologically active ingredient on their labels.¹⁶ This revision might have had an impact on cosmetic labeling if private formula drugs had been broadly defined to include many cosmetics.¹⁷ At best the bill could have been read to imply that a particular cosmetic, if likely to be used medicinally, could satisfy the definition of "drug" and therefore be required to bear a list of active ingredients on the label.¹⁸ Because of that possible implication the bill was vigorously opposed by the cosmetic industry.¹⁹ Industry representatives expressed the fear that the proposed bill would be interpreted to require the revelation of cosmetic formulae which would allow imitators to flood the cosmetic market with inferior products sold at lower prices and cause "serious losses" to the estab-

15. *Id.* § 352(e).

16. C. DUNN, FEDERAL FOOD, DRUG AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD 41 (1938) [hereinafter cited as DUNN].

17. *Id.* at 37.

18. *Id.* For the definition of a "drug" in the FDCA, see 21 U.S.C. § 321 (g)(1) (1970) *supra* note 14.

19. Counsel for the Associated Manufacturers of Toilet Articles testified that according to his interpretation of the bill, a hypothetical shaving lotion which bore on its label the statement "good for bleeding" therefore became at once a drug as well as a cosmetic and subject to disclosure requirements. In his opinion, the result could be a label replete with twenty or more chemical designations, essential oils, synthetic drugs, alcohol, fixatives, and other items which furnished no useful information to the consumer and disclosed valuable trade secrets to competitors. *Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce*, 73rd Cong., 2nd Sess. 293 (1933).

lished cosmetic industry.²⁰ They urged that a provision be added to explicitly bar any formulae disclosure requirement.²¹ The bill died in committee.²²

Two successor bills in 1934²³ suffered the same fate; neither included any provision for the ingredient labeling of cosmetics. However, testimony at Congressional hearings increasingly favored such a revision of the 1906 Act. For example, during hearings held before the Committee on Commerce, a physician specializing in allergic medicine estimated that about fifteen percent of the white population of the United States was allergic to one or more substances. He noted that on frequent occasions he had observed allergic reactions to cosmetics, primarily as a result of one particular ingredient, orris root.²⁴ The physician urged mandatory listing of the basic ingredients of cosmetics on their labels.²⁵

Still another bill to revise the Food and Drug Act, again without ingredient labeling requirements, was introduced in 1935.²⁶ Once again the need for disclosure of cosmetic ingredients was urged at hearings, this time by speakers representing various public interest organizations and such groups as the American Dietetic Association and the American Home Economics Association.²⁷ The most compelling justification urged upon the Committee for labeling requirements was the need to provide information to the allergic consumer which would enable him or her to avoid harmful substances. Support for this position was voiced by both a consulting chemist and an allergy sufferer, each of whom testified as to the desirability of requiring full disclosure of cosmetic ingredients.²⁸ The general consensus among those testifying before the Committee was that the proposed law, which did not include a labeling requirement, was necessary and laudable but did not go far enough.

On May 28, 1935, following debate and amendment, the bill was unanimously passed by the Senate and sent to the House of Representatives.²⁹ After three years of debate and delay the bill

20. *Id.* at 297-98.

21. *Id.* at 398.

22. DUNN, *supra* note 5 at 50.

23. *Id.* at 51 and 68.

24. Orris root is used in cosmetic preparations for two reasons: 1) its fleshy hue and mild fragrance; 2) its marked ability to retain its scent for a considerable period of time.

25. *Hearing on S. 2800 Before the Senate Comm. on Commerce, 73rd Cong., 2nd Sess.* 494 (1934).

26. S.5, 74th Cong., 1st Sess., 79 Cong. Rec. 100 (1935).

27. *Hearings on S. 5 Before a Subcomm. of the Senate Comm. on Commerce, 74th Cong., 1st Sess.* 34-5 (1935).

28. *Id.* at 218 and 304-10.

29. 79 Cong. Rec. at 8356 and 8400 (1935).

was finally passed by the House and signed into law by President Franklin D. Roosevelt on June 25, 1938,³⁰ as the Food, Drug and Cosmetic Act of 1938. Although the new law was far from perfect, it was a step forward in that it subjected cosmetics generally to federal regulatory control for the first time.

Voluntary Registration and Filing of Cosmetic Ingredients

Although attempts to include ingredient labeling requirements in the FDCA failed, the extensive hearing testimony in favor of ingredient labeling found in the Act's legislative history along with the Food and Drug Administration's increased receptiveness to meeting consumer needs finally spurred, in 1971, the giant cosmetic industry³¹ to fashion its own voluntary ingredient disclosure regulations.³² At the same time, consumer groups have continued to push for further mandatory ingredient disclosure provisions.

The Cosmetic, Toiletry, and Fragrance Association filed two petitions³³ with the FDA in August, 1971,³⁴ suggesting regulations providing for voluntary registration by producers of cosmetic products and voluntary filing of cosmetic ingredient lists. The Association's expressed rationale for these petitions was that availability to the FDA of the names and addresses of establishments producing cosmetic products as well as information on ingredients used in cosmetics would lead to more efficient enforcement of the FDCA and would therefore serve the public interest. The disclosure provided for was limited, however, by a section aimed at insuring confidentiality of ingredient filings by providing that these statements or any compilation of them constituted trade secrets or confidential information³⁵ and were exempt from public disclosure under both the Administrative Procedure Act (Freedom of Information Act)³⁶ and the FDCA.³⁷ Under the

30. DUNN, *supra* note 5 at 1015.

31. Whalley, *U.S. Sales of Cosmetics and Toilet Preparations*, SOAP, PERFUMERY & COSMETIC J., Apr. 1973, at 217-18. Conservative estimates place the annual gross income for the cosmetic industry during 1972 at four billion dollars.

32. The cosmetic industry later made a similar proposal for voluntary filing with the FDA of "cosmetic product experiences," that is, adverse reactions to cosmetics. 38 Fed. Reg. 28914-17 (1973).

33. Regulations proposed by the public are submitted for FDA consideration by means of petitions. The proposal, as defined in and limited by the petition, is then subject to public comment and hearings before the FDA to determine whether to adopt it, reject it or adopt it with modifications.

34. 36 Fed. Reg. 16934-37 (1971).

35. *Id.* at 16936.

36. 5 U.S.C. § 552(b)(4) (1970).

37. 21 U.S.C. § 331(j) (1970).

Association proposal, such information could be disclosed only in the course of testimony by an FDA employee in a court action brought by the FDA for enforcement of the Food, Drug and Cosmetic Act provisions.³⁸ Even then, disclosure could only be made *in camera* and only when the information was relevant to the violation charged.³⁹ The petitions further requested that if confidentiality of the statements could not be honored, the information provided to the FDA would be destroyed or returned to the submitting party.⁴⁰

The proposal on voluntary listing of ingredients did not include a requirement for exact quantitative information. The ingredients were to be listed in descending order of a predominance by weight (with the exception that fragrances and flavors could be designated as such without naming the component ingredients);⁴¹ the amount of each ingredient could be designated by one of seven quantitative ranges from over fifty percent to less than 0.1 percent.⁴² Under this proposal ingredient information is to be filed with the FDA rather than published on cosmetic product labels.⁴³

Between August 26, 1971, and September 25, 1971, the proposed regulations were open to public comment and twenty-two comments were received by the FDA Commissioner. In one of these comments a member of Congress urged mandatory rather than voluntary registration and filing of ingredient statements by cosmetic producers.⁴⁴ Other comments challenged the legality of *voluntary* regulations under the FDCA⁴⁵ and argued that authority now existed to require mandatory registration of cosmetic producers, filing of cosmetic statements, and labeling of ingredients on cosmetic products.

In reviewing these comments the Commissioner determined that he had the authority to accept both the voluntary registration and voluntary filing of cosmetic product ingredient statements.⁴⁶ He asserted that a regulation making such statements mandatory could result in lengthy litigation which would serve to seriously deter the FDA from obtaining the type of information expected from voluntary filings.⁴⁷ While the Commissioner recognized that the recommendation for ingredient labeling on cosmetics was meritorious and

38. 36 Fed. Reg. 16936 (1971).

39. *Id.*

40. *Id.* at 16936-37.

41. *Id.* at 16936.

42. *Id.*

43. *Id.* at 16935.

44. 37 Fed. Reg. 7151 (1972). The member of Congress was not named.

45. 21 U.S.C. § 301 *et seq.* (1970).

46. 37 Fed. Reg. 7151 (1972).

47. *Id.*

would help prevent deception of consumers and facilitate value comparisons, he concluded that this issue was not explicitly raised by the Cosmetic, Toiletry and Fragrance Association petition;⁴⁸ therefore, no regulation requiring ingredient labeling could be promulgated on the basis of that petition. He did note, however, that the possibility of publishing a proposal under the Fair Packaging and Labeling Act for labeling of sensitizing ingredients was presently under consideration.⁴⁹

In response to objections raised by a public interest group to the all-inclusive scope of the confidentiality provisions in the proposed voluntary disclosure regulation,⁵⁰ the Commissioner modified the proposal to make the confidentiality section conform to the Administrative Procedures Act.⁵¹ Accordingly, under the regulation as amended any information alleged to be a trade secret must be clearly marked as confidential by the submitting party and must be accompanied by a statement setting forth adequate grounds to justify its confidentiality.⁵² Furthermore, if the FDA concludes that an item so marked is not confidential material⁵³ and therefore not exempt from disclosure to the public, the person submitting the information must be informed and given an opportunity to appeal that decision to the Food and Drug Administration Assistant Commissioner for Public Affairs.⁵⁴

In April of 1972, the revised regulations concerning voluntary filing of ingredients⁵⁵ were published by the Commissioner. The following August, forms were available for voluntary filing of cosmetic ingredients and cosmetic raw material composition statements, and an effective date thirty days from issuance of the directive was established for the new regulation.⁵⁶ As of October, 1973, 754 manufacturing establishments and 7,200 formulae representing eighty percent of the cosmetic products sold in this country had been registered with the FDA.⁵⁷

48. *Id.*

49. *Id.* at 7152. See notes 58-63 and accompanying text *infra* for a discussion of regulations under the FPLA.

50. *Id.*

51. *Id.* The Administrative Procedures Act, 5 U.S.C. § 552(b)(4) (1970), provides that government agencies need not disclose information classified as a "trade secret" to the public.

52. 21 C.F.R. § 172.9 (1973).

53. That is, not "trade secrets . . . obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4) (1970).

54. 21 C.F.R. § 172.9 (1973). The Assistant Commissioner for Public Affairs makes the final decision as to confidentiality of the information.

55. 21 C.F.R. § 170 *et seq.* (1970).

56. 37 Fed. Reg. 17470 (1972). The forms are FD Form 2512 ("Cosmetic Product Ingredient Statement") and FD Form 2513 ("Cosmetic Raw Material Composition Statement").

57. HEW News, No. 73-46 (October, 1973).

THE FAIR PACKAGING AND LABELING ACT

The FDA's issuance of voluntary cosmetic ingredient labeling regulations in April of 1972, satisfied neither consumer groups nor the FDA itself. The FDA turned to the Fair Packaging and Labeling Act for authority to promulgate mandatory ingredient labeling requirements.

The Fair Packaging and Labeling Act (FPLA),⁵⁸ popularly known as the "Truth in Packaging" act, was first introduced in the Senate in 1965, and was signed into law on November 3, 1966. The congressional purpose in enacting this legislation was to enable consumers to make value comparisons of similar products sold under different brand names. The lawmakers believed value comparisons would be made possible by requiring the manufacturer to include on the product labels accurate quantity information.⁵⁹ Apparently the need for ingredient information necessary to make quality comparisons among cosmetics was not considered. The law deals with the packaging and labeling of retail consumer commodities,⁶⁰ which include cosmetics,⁶¹ but only quantity labeling rather than ingredient labeling is required.

The FDA is charged with regulation of food, over the counter drugs, certain medical devices, and cosmetics, all of which are also subject to the Fair Packaging and Labeling Act requirements. A significant section of the FPLA provides that the agency given authority to promulgate regulations over commodities covered by the FPLA may issue additional regulations under the authority of the FPLA which are necessary to prevent the deception of consumers or to facilitate value comparisons of any consumer commodity.⁶² Under the Act the Secretary of Health, Education and Welfare, and through him the FDA, assumes this authority to promulgate additional regulations of food, drugs and cosmetics.⁶³ Under this authority the FDA considered issuing a regulation requiring mandatory labeling of sensitizing cosmetic ingredients.⁶⁴

58. 15 U.S.C. § 1451 *et seq.* (1970).

59. *Id.* § 1451.

60. *Id.* § 1452(a).

61. Retail consumer commodities are defined as:

Any food, drug, device or cosmetic (as those terms are defined in the Federal Food, Drug and Cosmetic Act), and any other article, product or commodity of any kind or class which is customarily produced or distributed for sale through retail sales agencies or instrumentalities for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and which usually is consumed or expended in the course of such consumption or use.

Id. § 1459(a).

62. *Id.* § 1454(c).

63. *Id.* § 1454(a).

64. 37 Fed. Reg. 7151 (1972).

Mandatory Cosmetic Ingredient Labeling Requirements

While the FDA-proposed regulation was under consideration a consumer petition⁶⁵ was submitted to the FDA calling for regulation of cosmetic ingredient labeling.⁶⁶ In the statement of grounds for such regulation, the petitioners referred to the fact that the FDA was considering a proposal under the FPLA for the labeling of *sensitizing* ingredients.⁶⁷ The petitioners agreed that this would contribute toward protecting those Americans who suffer from allergic reactions; however, they did not believe such labeling would fully inform consumers and enable them to make value comparisons. They contended that full ingredient labeling would promote fair and efficient functioning of a free market economy by allowing consumers to "vote with their pocket-books" and increase the competitive posture of the marketplace. Labeling is also important to the consumer as a health measure and any cosmetic product which is injurious has no value whatsoever and may in fact impose a significant risk on the buyer. "There is no benefit-risk ratio with respect to cosmetics."⁶⁸ Their petition, like the FDA proposal, relied on the disclosure of procedures established under the FPLA⁶⁹ to protect both the interest of consumers in knowing the ingredients of a cosmetic preparation and manufacturers' interest in protecting trade secrets.⁷⁰

The consumer and FDA proposals were substantially similar.⁷¹ Both proposals included provision for labeling of ingredients in decreasing order of predominance on a principal display panel. However, the consumer proposal dealt more directly with trade secret exceptions and the handling of trade secret information in emergency situations,⁷² while the FDA proposal apparently concentrated on remedying the problems created by technical and ambiguous terms that could be placed on the label.⁷³

65. 38 Fed. Reg. 3523-24 (1973). On May 17, 1972, a petition was submitted by Professor Joseph A. Page of Georgetown University, Anthony L. Young, a student at the University, and the Consumer Federation of America.

66. *Id.* at 3524.

67. *Id.*

68. 38 Fed. Reg. 3523-24 (1973).

69. 15 U.S.C. § 1454(c)(3) (1970).

70. 38 Fed. Reg. 3524 (1973).

71. See 21 C.F.R. § 172.1 *et seq.* (1970).

72. 38 Fed. Reg. 3524 (1973). Under this proposal such information could be made available on request to poison control centers and to licensed physicians when necessary to assist in determining the cause of an adverse patient reaction. Alternatively, any packager of cosmetics could supply the FDA with information on diagnostic or remedial procedures adequate to permit evaluation and treatment in emergency situations.

73. 21 C.F.R. § 172.5-172.6 (1973). The specific provisions for ingredient designation are sections 172.6(c)-(d).

Two-hundred and ninety-one comments were received in response to the two proposals. These came from consumers, the cosmetic industry, a government agency, trade and professional associations and the like. An overwhelming majority of the comments (273) endorsed cosmetic ingredient labeling.⁷⁴ Several comments questioned the legal basis for the proposals, contending that the FPLA granted authority to establish ingredient labeling only on a commodity-by-commodity basis and only as necessary to prevent consumer deception or to facilitate value comparison. The Commissioner concluded that for the purposes of ingredient labeling, all cosmetics are appropriately considered a single "commodity" and that ingredient labeling is necessary to prevent deception and facilitate value comparisons.⁷⁵ Relying upon the United States Supreme Court's decision in *Weinberger v. Hynson, Westcott & Dunning*,⁷⁶ the Commissioner decided that the most effective means of instituting the labeling requirement would be to issue a comprehensive order governing the entire spectrum of cosmetic products.⁷⁷

Many of the comments received by the FDA related to the trade secret portion of the proposals, the meaning of cosmetic ingredient names, and the method of declaring flavor, fragrance and color.⁷⁸ In response, the Commissioner admitted that since the FPLA does provide for protection of trade secrets, the regulation must make provision for them.⁷⁹ Further, the Commis-

74. 38 Fed. Reg. 289.2 (1973). Of those comments endorsing cosmetic ingredient labeling, eight specifically favored the consumer proposal (38 Fed. Reg. 3523-24 (1973)), and thirteen specifically endorsed the Commission proposal (21 C.F.R. § 172.1 *et seq.* (1973)), ten were in opposition to both proposals, and eight expressed neither endorsement nor opposition, but requested modification or clarification.

75. 38 Fed. Reg. 38912 (1973).

76. 412 U.S. 609 (1973). In *Weinberger*, the Court held *inter alia* that the FDA's administrative procedure of bringing together all manufacturers of a given drug for a single hearing on proposed removal of the drug from the market for safety or efficacy reasons did not deny individual manufacturers procedural due process. *Id.* at 625.

77. 38 Fed. Reg. 28912 (1973). See note 6 *supra* for categories of cosmetic products.

78. *Id.*

79. *Id.* The confidentiality provisions are found in 21 C.F.R. § 172.9 (1973) which provides:

(a) Each item of information contained in, attached to, or included with FD Forms 2512, 2513, 2514, and amendments thereto and constituting a trade secret or other privileged and confidential commercial information exempt from disclosure to the public must be clearly marked as confidential. Each item of information so marked must be accompanied by a statement setting forth adequate grounds to justify its confidentiality. If the Food and Drug Administration concludes that an item so marked is not exempt from disclosure to the public, the person submitting the information will be informed and will be given an opportunity to appeal that decision to the Assistant Commissioner for Public Affairs, whose decision on the matter will be final.

sioner recognized possible problems of definition and declared that a new compendium or dictionary compiled by the Cosmetic, Toiletry and Fragrance Association would be the controlling authority on ingredient terms.⁸⁰ In regard to color and fragrance, the Commissioner concluded that some provision should be made for listing colors by name, even if the number of fragrances and flavors would make their listing impractical.

The Regulation

The final regulation relating to cosmetic ingredient labeling was published in the Federal Register in October, 1973.⁸¹ All cosmetic labels ordered after March 31, 1974, and all cosmetic products labeled after March 31, 1975, are to comply with the regulation which requires that ingredients be listed prominently and conspicuously on any appropriate information panel in decreasing order of predominance (except for fragrances and flavors) and that all ingredients be listed by standardized names.⁸² If a package is too small, a tag or card with the required ingredient information must be securely attached to the container.⁸³

Two details should be noted. Since this regulation is based on the FPLA, it applies only to those products actually labeled after the effective date of March 31, 1975. Products already labeled and in inventory and products in distribution channels will not be affected. However, many companies have already complied with the labeling requirements and at least by the end of 1975 all cosmetics bearing labels without the new disclosures will have been phased out. Secondly, sanctions which are provided for the FDA include only civil actions: a civil seizure of goods on the market or a request for an injunction. Criminal prosecution of offenders is not permitted under the FPLA. However, the civil remedy should be sufficient to insure enforcement be-

(b) Data and information otherwise exempt from public disclosure may be revealed in administrative or court enforcement proceedings where the data or information are relevant. Any such use will be in a manner that reduces public disclosure to the minimum necessary under the circumstances.

(c) Data and information otherwise exempt from public disclosure may be disclosed to consultants, advisory committees, and other persons who are special government employees. Such persons are thereafter subject to the same restrictions with respect to disclosure as any Food and Drug Administration employee.

80. 38 Fed. Reg. 28912. The compendium is known as the CTFA Cosmetic Ingredient Dictionary. If the CTFA Dictionary did not contain an appropriate listing, the Commissioner determined that other compendia enumerated in the regulations would control the designation. See 21 C.F.R. § 172.5(d)(2) (1973).

81. 38 Fed. Reg. 28913-14 (1973).

82. *Id.*

83. *Id.*

cause of the potency of injunctive action. If there is a violation of the injunction the accompanying contempt proceedings would allow for as complete court supervision as there would be in a criminal prosecution.

CONCLUSION

In the last two and one-half years since the first proposal by the cosmetic industry for voluntary filing of ingredients of cosmetic products, substantial advances have been made in the regulation of cosmetics. In 1975, when the regulation requiring full ingredient labeling becomes effective, the hazard to consumers from reactions to unknown ingredients in cosmetics will be greatly diminished. In addition, consumers will be able to compare cosmetic products to determine for themselves whether the product costing five dollars is really worth ten times more than the product costing fifty cents.

From the inception of the Food, Drug and Cosmetic Act in 1938, few changes in the regulation of cosmetic labeling have been won by consumers. It is only now, in a period of heightened consumer consciousness and increasing realization by both the government and industry of the need to respond to consumer that ingredient information has finally reached the cosmetic label.