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THE COSMETIC INDUSTRY

SCIENTIFIC AND REGULATORY FOUNDATIONS

Edited by

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THE COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION, INC.
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I. BASIC PRINCIPLES

A. The Federal Food, Drug, and Cosmetic Act; the Fair Packaging and Labeling Act; and the Food and Drug Administration

In the United States, the composition and labeling of cosmetic products are governed primarily by the Federal Food, Drug, and Cosmetic Act (FDC Act)[1] and by the Fair Packaging and Labeling Act (FPLA).[2] These acts are enforced by the U.S. Food and Drug Administration (FDA), an agency of the Department of Health and Human Services (formerly the Department of Health, Education and Welfare).[3]

B. Definition of "Cosmetic"

The term "cosmetic" is defined by section 201(i) of the FDC Act as follows:

> (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, or introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.[4]

This definition is incorporated by reference in the FPLA.[5] If an article comes within this definition, it is subject to regulation as a "cosmetic" under the FDC Act and the FPLA.

II. COMPOSITION OF COSMETIC PRODUCTS

A. Prohibition of "Poisonous or Deleterious Substances"

Except for color additives (discussed in Sec. II.D), there is no official listing of ingredients "approved" for cosmetic use. Instead, section 601(a) of the FDC Act provides generally that a cosmetic shall be deemed to be "adulterated":

> If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual....[6]

Accordingly, manufacturers are under a general duty to avoid use of any cosmetic ingredient that may render the finished product injurious to users under expected conditions of use.

B. Regulations Restricting Particular Ingredients

The FDA has published regulations explicitly prohibiting or restricting use of the following ingredients in cosmetic products: bithionol,[7] mercury compounds,[8] vinyl chloride,[9] halogenated salicylanilides,[10] zirconium in aerosol products,[11] chloroform,[12] chlorofluorocarbon propellants,[13] and hexachlorophene.[14] The FDA would consider violative products to be adulterated within the meaning of section 601(a) of the FDC Act.

These regulations prohibiting or restricting use of certain ingredients do *not*, however, purport to be a complete listing of all ingredients that should not be used in cosmetics. The FDA may initiate regulatory action (as described in Sec. IV.A) whenever it concludes that a particular ingredient used in a cosmetic product violates the standard of section 601(a) of the FDC Act.

C. Regulation Requiring Safety Substantiation

The FDA has published a regulation stating that manufacturers have a general duty to substantiate the safety of each ingredient and finished product prior to marketing:

> Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:
>
> *Warning* – The safety of this product has not been determined.[15]

D. Color Additives

Pursuant to the Color Additive Amendments of 1960 to the FDC Act, color additives are regulated in a different manner than other cosmetic ingredients.[16] A color additive may not be used in a cosmetic product unless such use first has been approved by an FDA regulation.

The FDA has published numerous regulations listing particular colors authorized for use in cosmetics.[17] For certain of these colors, FDA approval ("certification") of each production batch of the color also is required.

E. Coal-Tar Hair Dyes

The general prohibition against use of a "poisonous or deleterious substance," established by section 601(a) of the FDC Act (discussed in Sec. II.A), does not apply to coal-tar hair dyes. Instead, section 601(a) requires that a specific caution appear on the label of a coal-tar hair dye product:

> Caution – This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.[18]

Coal-tar hair dyes also are exempt from the general requirement for FDA approval of color additives used in cosmetics.[19]

Assuming that a coal-tar hair dye product bears the foregoing cautionary statement, insofar as section 601(a) and the Color Additive Amendments are concerned, a manufacturer may use any coal-tar ingredient(s) in the product.

III. LABELING

A. Labeling Requirements – Generally

Pursuant to the FDC Act, the FPLA, and FDA regulations, cosmetic products generally are required to provide the following information on their labels:

1. A statement of the identity of the product
2. A statement of the net quantity of contents
3. A statement of the name and place of business of the manufacturer, packer, or distributor
4. A list of the ingredients included in the product; and for certain products
5. Cautionary or warning language

Before reviewing these various labeling requirements, it is important to note a distinction between requirements imposed pursuant to the FDC Act and requirements imposed pursuant to the FPLA: Generally, labeling requirements premised on the FDC Act must appear *both* on the immediate container of the cosmetic product *and* on the outside container or wrapper of the retail package.[20] Labeling requirements premised on the FPLA must appear *only* on the *outside* container or wrapper of the retail package.[21] Also, certain label statements are required by FDA regulations to appear on the "principal display panel,"[22] while other mandatory labeling information may appear elsewhere on the label.

A cosmetic product that fails to bear required labeling information is deemed to be "misbranded" and is subject to regulatory action by the FDA. (See Sec. IV.A concerning FDA enforcement.)

B. Statement of Identity

Pursuant to FDA regulations premised on the FPLA, the principal display panel of the outside container or wrapper of the retail package of a cosmetic product must bear a statement of the identity of the product.[23]

This statement must be in terms of the "common or usual name" of the product, or "an appropriately descriptive name," or, "when the nature of the cosmetic is obvious, a fanciful name understood by the public to identify such a cosmetic," or "an appropriate illustration or vignette representing the intended cosmetic use."[24]

C. Net Quantity of Contents

Pursuant to the FDC Act and FDA regulations premised on both the FDC Act and the FPLA, a statement of the net quantity of contents must appear both on the immediate container of the cosmetic product and on the principal display panel of the outside container or wrapper of the retail package.[25]

The quantity may be stated in terms of weight, measure, or numerical count.[26]

Customary English units of measure must be used (avoirdupois ounces, fluid ounces, etc.).[27] Metric measure may be declared in addition, but the net quantity of contents declaration may not be solely in terms of metric units.[28]

The regulations provide numerous specific requirements with respect to the format, type size, and placement of information about net quantity of contents.[29]

D. Name and Place of Business of Manufacturer, Packer, or Distributor

Pursuant to the FDC Act and FDA regulations premised on both the FDC Act and the FPLA, the name and place of business of the manufacturer, packer, *or* distributor must be declared both on the immediate container and on the outside container or wrapper of the retail package.[30] The information is not required to be on the principal display panel of the package.

Note the "or": The actual manufacturer (e.g., a contract manufacturer) need not be identified if the packer or distributor is identified.

E. Listing of Ingredients

Pursuant to FDA regulations premised on the FPLA, the outside container or wrapper of the retail package of a cosmetic product must declare the ingredients contained in the product.[31] The information is not required to be on the principal display panel.

Generally, ingredients must be declared in descending order of predominance, although ingredients present at concentrations of not more than 1 percent and color additives may be grouped separately and declared at the end of the ingredient listing without regard to order of predominance. The CTFA (Cosmetic, Toiletry and Fragrance Association, Inc.) *Cosmetic Ingredient Dictionary*, explicitly incorporated into the FDA regulations, is the most comprehensive source of approved nomenclature for cosmetic ingredient labeling.[32]

Ingredients that have been accepted by the FDA as having trade-secret status need not be identified by name, but are required to be designated in the ingredient listing by the phrase "and other ingredient(s)."[33]

F. Warnings or Caution Statements

Pursuant to the FDC Act or FDA regulations premised on that act, warnings or caution statements are required both on the immediate container and on the outside container or wrapper of certain cosmetic products. The coal-tar hair dye warning established by section 601(a) of the FDC Act has been discussed in Sec. II.E. The warning required by FDA regulations for products whose safety has not been substantiated has been discussed in Sec. II.C. In addition, the FDA has issued regulations requiring warnings for cosmetics in self-pressurized containers[34] and for feminine deodorant sprays.[35] A regulation requiring a warning for bubble bath products has also been published, but this requirement has been stayed pending reconsideration.[36]

G. Exemptions

The FPLA was passed by Congress to facilitate value comparisons by consumers when making purchasing decisions. Accordingly, cosmetic products intended for use solely as free samples, or otherwise not intended to be sold to consumers (e.g., products intended to be used in beauty salons or as theatrical makeup) are exempt from FPLA requirements.[37] This exemption is important particularly in the case of ingredient labeling, which is required only pursuant to the FPLA. Thus, for example, free samples or products intended for use solely in beauty salons are not required to bear cosmetic ingredient labeling.

H. Prohibition of False or Misleading Labeling

All cosmetics are subject to a general prohibition against false or misleading labeling. Section 602(a) of the FDC Act provides that a cosmetic shall be deemed to be misbranded:

> If its labeling is false or misleading in any particular.[38]

B. Imports and Exports

Special provisions apply in the case of imports and exports.

With respect to imports, the FDA may request the U.S. Customs Service, within the Department of the Treasury, to detain any cosmetic product offered for import that "appears" to be adulterated or misbranded.[50] FDA regulations provide for an informal hearing if an importer wishes to challenge an import detention.[51]

With respect to exports, the FDC Act provides that a cosmetic intended for export "shall not be deemed to be adulterated or misbranded" if it:

> (A) accords to the specifications of the foreign purchaser,
> (B) is not in conflict with the laws of the country to which it is intended for export,
> (C) is labeled on the outside of the shipping package that it is intended for export, and
> (D) is not sold or offered for sale in domestic commerce.[52]

Thus, a cosmetic intended for export may, for example, include ingredients not permitted in the United States, or omit labeling required in the United States, *if* it complies with the foregoing criteria.

C. Voluntary Reporting Programs

Cosmetics are subject to three voluntary reporting programs established by FDA regulations. These include:

1. Voluntary registration of manufacturing and packing establishments.[53] More than 950 companies have registered with the agency.[54]
2. Voluntary reporting of cosmetic raw materials and cosmetic product ingredients.[55] More than 3,600 raw materials and more than 19,500 finished product formulations have been registered with the agency.[56]
3. Voluntary reporting of cosmetic product experiences, including information about adverse reactions.[57] More than 70 companies currently are participating.[58]

The FDA has issued standard reporting forms, available from FDA district offices or from the FDA's Division of Cosmetics Technology at FDA headquarters in Washington, D.C., for use by companies that participate in the voluntary reporting program.

V. OTHER MATTERS

A. The Cosmetic Ingredient Review

The Cosmetic, Toiletry, and Fragrance Association (CTFA)[59] has established a comprehensive industry-funded program for reviewing the

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sociation (CTFA)[59] has es-
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safety of cosmetic ingredients: the Cosmetic Ingredient Review (CIR).

Under the CIR program, an independent Expert Panel of scientists has been commissioned to evaluate the available literature, published and unpublished, on the safety of cosmetic ingredients. A permanent CIR staff is located in Washington, D.C. There is a liaison representative to the Expert Panel both from consumer organizations and from the cosmetic industry. In addition, the FDA has appointed one of its employees as a "contact person" to participate in Expert Panel proceedings.

Following peer review, panel reports assessing the safety of cosmetic ingredients are published by the CIR in a scientific journal.[60]

B. Cosmetic Drugs

Section 201(g) of the FDC Act defines a "drug" as including:

> articles intended for use in the...cure, mitigation, treatment, or prevention of disease in man...and...articles (other than food) intended to affect the structure or any function of the body of man....[61]

The "intended use" of an article may be determined by reference to the claims made for it in labeling or advertising.[62] Depending on the claims, a particular product may be subject to regulation as a cosmetic, a drug, or both.

Pursuant to section 201(g), certain cosmetic-type products have been subjected to regulation as drugs by the FDA. Examples include toothpastes represented to prevent tooth decay, antiperspirants, tanning products represented to prevent sunburn, and lip balm products represented to prevent chapping.

It is important to recognize that "drug" status entails significant consequences for a would-be cosmetic. Drugs are subject to different requirements with respect to manufacture, composition, and labeling, and to different FDA enforcement priorities. For example, drug manufacturers are required to register with the FDA their manufacturing establishments and each of their drug products.[63] The FDA has published regulations establishing minimum "current good manufacturing practice" (CGMP) requirements for drugs.[64] Labeling and composition may be subject to an applicable over-the-counter (OTC) drug monograph.[65] Active ingredients in drug products must be identified on the immediate container as well as on the outside container or wrapper.[66] Furthermore, drug establishments are likely to be inspected more often than are cosmetic establishments.[67]

For more information about cosmetic drugs, see Chap. 5.

C. Soap

The definition of cosmetic, quoted in Sec. I.B, explicitly excludes "soap."

The FDA has published a regulation interpreting the meaning of "soap" for the purpose of the cosmetic definition.[68] The FDA regulation takes the position that the "soap" exemption from the cosmetic definition applies only to articles that meet the following conditions:

> (1) The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to the alkali-fatty acid compounds; and
>
> (2) The product is labeled, sold, and represented only as soap.

If a product is a soap, it is exempt from the FDA's cosmetic regulations. Thus, for example, a soap may be manufactured with colors that are not approved for use in cosmetics, and a soap is not required to bear ingredient labeling.

Although exempt from cosmetic regulation under the FDC Act, soap products are subject to "consumer product" regulation by the Consumer Product Safety Commission (CPSC) and to labeling requirements established by the Federal Trade Commission (FTC). For more information about soap, see Chap. 4.

D. The Consumer Product Safety Commission

Cosmetics, as defined in the FDC Act, are explicitly excluded from regulation under the Consumer Product Safety Act[69] and the Federal Hazardous Substances Act,[70] the primary statutory authority of the Consumer Product Safety Commission (CPSC).

However, the CPSC has asserted authority over cosmetic-type products in a few respects: The CPSC has authority to regulate soap products, since "soap" does not come within the FDC Act definition of "cosmetic"; the CPSC asserts authority to regulate mechanical hazards presented by cosmetic product *containers*;[71] and the commission has authority under the Poison Prevention Packaging Act[72] to issue regulations establishing special packaging standards required to protect children from serious personal injury or illness.

E. Federal Trade Commission Regulation of Advertising

Advertising for cosmetic products (as distinguished from *labeling*) is regulated by the Federal Trade Commission (FTC), not the FDA. For information about the FTC, see Chap. 6.

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F. Regulation by the States

In addition to federal regulation of cosmetics by the FDA, the individual states have the authority to regulate these products and to impose requirements that are not in conflict with federal provisions.

VI. CONCLUSION

In summary, the composition and labeling of cosmetic products offered for sale in the United States are regulated by the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and regulations issued by the U.S. Food and Drug Administration. These requirements operate generally to prohibit the inclusion of harmful ingredients and to require informative labeling. Mandatory federal regulation is supplemented by a voluntary reporting program administered by the FDA, and by the industry-funded Cosmetic Ingredient Review evaluation of the safety of cosmetic ingredients. Products represented to affect the structure or function of the body, such as anticavity toothpastes or antiperspirants, are subject to regulation by the FDA as drugs. Soap is excluded from FDA cosmetic regulation and instead is subject to regulation by the Consumer Product Safety Commission and the Federal Trade Commission. Finally, the individual states have independent authority to establish regulatory requirements that are not in conflict with federal provisions.

NOTES

1 21 U.S. Code (U.S.C.) 301 et seq.
2 15 U.S.C. 1451 et seq.
3 The authority vested in the Secretary of Health and Human Services by the FDC Act and the FPLA has been delegated to the Commissioner of Food and Drugs, who directs the FDA. 21 Code of Federal Regulations (C.F.R.) 5.1(a).
4 21 U.S.C. 321(i).
5 15 U.S.C. 1454, 1456, 1459(a).
6 21 U.S.C. 361(a).
7 21 C.F.R. 700.11.
8 21 C.F.R. 700.13.
9 21 C.F.R. 700.14.
10 21 C.F.R. 700.15.
11 21 C.F.R. 700.16.
12 21 C.F.R. 700.18.
13 21 C.F.R. 700.23.
14 21 C.F.R. 250.250.
15 21 C.F.R. 740.10(a).
16 21 U.S.C. 321(t), 361(e), 362(e), 376.
17 21 C.F.R. 73, 74, 81, 82.

18 21 U.S.C. 361(a).
19 21 U.S.C. 361(e).
20 21 U.S.C. 321(k).
21 15 U.S.C. 1459(b).
22 21 C.F.R. 701.10.
23 15 U.S.C. 1453(a)(1); 21 C.F.R. 701.11.
24 21 C.F.R. 701.11(b).
25 21 U.S.C. 362(b)(2); 15 U.S.C. 1453(a)(2); 21 C.F.R. 701.13.
26 21 U.S.C. 362(b)(2); 15 U.S.C. 1453(a)(2); 21 C.F.R. 701.13.
27 15 U.S.C. 1453(a)(3); 21 C.F.R. 701.13(j), (k), (o), (p).
28 15 U.S.C. 1453(a)(3); 21 C.F.R. 701.13(j), (k), (o), (p), (r).
29 See generally 21 C.F.R. 701.13.
30 21 U.S.C. 362(b)(1); 15 U.S.C. 1453(a)(1); 21 C.F.R. 701.12.
31 15 U.S.C. 1454(c)(3); 21 C.F.R. 701.3.
32 21 C.F.R. 701.3(f); 21 C.F.R. 701.3(c)(2).
33 21 C.F.R. 701.3(a).
34 21 C.F.R. 740.11.
35 21 C.F.R. 740.12.
36 21 C.F.R. 740.17, published in *Fed. Reg.* *45*:55172 (August 19, 1980). Notice of interim stay pending reconsideration published in *Fed. Reg.* *48*:7169, 7203-7204 (February 18, 1983).
37 15 U.S.C. 1451; FDA Inspection Operations Manual, section 694, Cosmetics, Exhibit 694.1-B, para. 1, Cosmetic Ingredient Labeling (TN 80-6), February 29, 1980.
38 21 U.S.C. 362(a).
39 FDA Regulatory Procedures Manual, part 8, Compliance, chaps. 8-10, Notice of Adverse Findings and Regulatory Letters, September 1980.
40 FDA Regulatory Procedures Manual, part 8, Compliance, chap. 8-10, Notice of Adverse Findings and Regulatory Letters, September 1980, p. 7.
41 FDA Regulatory Procedures Manual, part 8, Compliance, chap. 8-10, Notice of Adverse Findings and Regulatory Letters, September 1980, pp. 7-8.
42 21 C.F.R. 7.40-7.59.
43 21 C.F.R. 7.40(b).
44 21 U.S.C. 334.
45 21 U.S.C. 332.
46 21 U.S.C. 331, 333.
47 15 U.S.C. 1456.
48 FDA Talk Paper T80-52, "FDA Budget for FY 1981," December 18, 1980.
49 H. J. Eiermann, Cosmetic Regulatory Update – 1980, presented at Annual Educational Conference of the Food and Drug Law Institute, December 10, 1980, p. 13. (Mr. Eiermann is the Director of FDA's Division of Cosmetics Technology.) The number of inspections fluctuates from year to year. At the time of final edit-

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53(a)(2); 21 C.F.R. 701.13.
53(a)(2); 21 C.F.R. 701.13.
)1.13(j), (k), (o), (p).
)1.13(j), (k), (o), (p), (r).

53(a)(1); 21 C.F.R. 701.12.
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. *Reg.* 45:55172 (August 19,
ıg reconsideration published in
uary 18, 1983).
erations Manual, section 694,
, Cosmetic Ingredient Labeling

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d Regulatory Letters,

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et for FY 1981," December

y Update – 1980, presented
the Food and Drug Law In-
(Mr. Eiermann is the Director
nology.) The number of in-
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ing of this chapter, it appears that the FDA may conduct more than 900 cosmetic establishment inspections in 1983, although more than half of these are planned to be fairly cursory "abbreviated inspections."

50 21 U.S.C. 381.
51 21 C.F.R. 1.94.
52 21 U.S.C. 381(d)(1).
53 21 C.F.R. 710.
54 Statistics for the Voluntary Cosmetics Registration Program, Division of Cosmetics Technology (FDA), October 1, 1980.
55 21 C.F.R. 720.
56 See note 54.
57 21 C.F.R. 730.
58 See note 54.
59 The Cosmetic, Toiletry and Fragrance Association (CTFA) is the national trade association representing manufacturers and distributors of cosmetic, toiletry and fragrance products in the United States. The CTFA's offices are at 1110 Vermont Avenue, N.W., Suite 800, Washington, D.C. 20005. The CTFA includes more than 250 companies that manufacture or distribute approximately 90 percent of the finished cosmetic products marketed in the United States. In addition, the CTFA includes more than 230 associate member companies from related industries, such as manufacturers of cosmetic raw materials and packaging materials.
60 See *J. Environ. Pathol. Toxicol.* 4(4):2ff (October 1980).
61 21 U.S.C. 321(g)(1).
62 For example, *United States* v. *"Sudden Change,"* 409 F.2d 734, 739 (2d Cir. 1969). "The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put." S. Rep. No. 361, 74th Cong., 1st Sess. (1935), quoted in C. W. Dunn, *Federal Food, Drug, and Cosmetic Act*, Stechert & Co., N.Y.C., 1938, p. 240.
63 21 U.S.C. 360.
64 21 C.F.R. 210, 211.
65 21 C.F.R. 330.
66 21 U.S.C. 321(k), 352(e)(1).
67 21 U.S.C. 360(h).
68 21 C.F.R. 701.20.
69 15 U.S.C. 2051 et seq. Section 3(a) of the Consumer Product Safety Act provides that the term "consumer product" does not include "cosmetics...as...defined in [the FDC Act]."
70 15 U.S.C. 1261 et seq. Section 2(f) of the Federal Hazardous Substances Act provides that the term "hazardous substance" does not apply to "cosmetics subject to" the FDC Act.
71 CPSC Advisory Opinion No. 229, December 15, 1975.
72 15 U.S.C. 1471. Section 2(2) of the Poison Prevention Packaging Act specifically includes "cosmetic" within the act's definition of "household substance."