

'Cosmeceutical' Classification In Regulatory Crosshairs

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Cosmetics are a large, competitive and growing area of the U.S. economy. Sales of cosmetics continue to increase year over year. In 2002, the U.S. cosmetics industry generated over \$40 billion in revenue. In 2014, that figure rose to about \$60 billion.[1] Major U.S. cosmetics companies include Sally Beauty Holdings Inc., Ulta Salon, Cosmetics & Fragrance Inc., Sephora USA Inc., L Brands Inc. (Bath & Body Works, Victoria's Secret) and L'Oreal SA (The Body Shop International).



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Cosmetics include, but are not limited to, products for hair (e.g., shampoos, conditioners, hair sprays and hair straighteners), skin (e.g., lotions, oils, powders, creams, bubble baths, perfume, colognes and toilet waters), eyes (e.g., makeup, mascara, eyebrow pencils, eyeliner and eye shadow), nails (e.g., nail polish) and oral care products (e.g., mouthwashes and breath fresheners).[2]

The U.S. Food and Drug Administration, which regulates drugs and biological products also regulates cosmetics through its authority under the Federal Food, Drug, and Cosmetic Act, primarily to ensure that cosmetics are not adulterated or misbranded.[3][4] The labeled intended use between a cosmetic product and a drug can be subtle, as shown by the following representative examples:

Cosmetic	Drug
Suntan Product	Sunscreen Product
Deodorant	Antiperspirant
Toothpaste	Anticavity Toothpaste
Skin Moisturizer	Wrinkle Remover

While the FDA regulates cosmetics under the FDCA, the Federal Trade Commission also regulates the advertising of cosmetics under the FTC Act, to ensure against unfair or deceptive acts or practices and the making of false and unsupported claims.[5] Thus, cosmetics manufacturers must comply with FDA regulations and FTC advertising regulations to legally market their products.

Cosmeceuticals

In order to gain competitive advantage and increase market share, some cosmetics companies have made, or advertised their product as being, both a cosmetic and a drug (i.e., a cosmeceutical).[6] However, there is not an FDA classification — statutory or regulatory — for this combination of product, nor recognition of a category of product called “cosmeceutical.” Thus, if a cosmetic contains a drug, it must comply with both the FDA’s requirements for a cosmetic and for a pharmaceutical. Put differently, the cosmetic containing the drug must not be adulterated,[7] not be misbranded,[8][9] and must generally comply with: (1) monograph requirements (for an over-the-counter drug) or (2) have been approved by the FDA prior to coming to market through a new drug application or an abbreviated new drug application. The FDA has authority to take enforcement actions on adulterated or misbranded cosmetics including, seizing the adulterated or misbranded product, seeking an injunction to prevent the company from making and distributing the adulterated or misbranded product and seeking criminal penalties.[10]

Cosmetic companies have attempted to make drug claims for cosmetics that do not actually contain a drug. When the FDA finds claims that would render a cosmetic to be a drug under the FDCA, the FDA will take enforcement action, including issuing a warning letter to the manufacturer,[11] which requires prompt action to correct the stated violations, and can include destroying inventory, relabeling product, corrective messaging to the market place and fines and penalties.

Cosmetic claims in advertising are also investigated by the FTC. If the FTC determines that the advertisements are not supported by competent and reliable scientific data, constitute unfair or deceptive acts or practices, or are simply false, the FTC can separately pursue enforcement action against the manufacturer. FTC enforcement action can result in consent decrees that require strict controls and oversight for promotional messaging and, in some instance, a money judgment in the form of redress or disgorgement. Class actions and shareholder lawsuits can also follow in the wake of a settlement with the FTC.

Typically, cosmetic claims can be divided into two categories: subjective and objective claims. Subjective claims (e.g., “Because I’m worth it”) are not generally of concern to the FTC or the FDA because the agencies consider it unlikely that consumers would believe these claims are supported by science. Objective claims, which make an objective representation (e.g., clinically proven), need appropriate support. When cosmetics manufacturers label their product with an objective claim that is not appropriately supported, they have both misbranded their product and violated FTC advertising regulations.

L’Occitane's "Almond Beautiful Shape" and "Almond Shaping Delight" Skin Creams

On March 27, 2014, the FTC issued a complaint against L’Occitane Inc., regarding its Almond Beautiful Shape and Almond Shaping Delight skin creams.[12][13] The FTC issues an administrative complaint when it has reason to believe that the law has been or is being violated and it appears to the commission that a proceeding is in the public interest. The complaint alleged that L’Occitane disseminated or caused to be disseminated advertisements for Almond Beautiful Shape and Almond Shaping Delight, which included the following statements:

- L'Occitane has harnessed nature's secret, with body-sculpting almond extracts cultivated in the south of France. We've teamed up with the shaping experts to bring you a firmer, smoother body ... and it's all just four weeks away![14]
- Almond Shaping Delight — three out of four women saw firmer, lifted skin. This luxuriously lightweight massage gel instantly melts into the skin to help visibly refine and sculpt the silhouette. Reported by 25 women after four weeks.[15]
- Almond Beautiful Shape Trims 1.3 inches in just four weeks. This ultrafresh gel cream helps to visibly reduce the appearance of cellulite, while smoothing and firming the skin. Centimetric loss measurement of thigh circumference.[16]
- This ultrafresh gel cream helps to visibly reduce the appearance of cellulite and to slim the thighs and buttocks, while smoothing and firming the skin.[17]
- Anti-fat storage: Slows the appearance of new fat cells on the thighs and buttocks with Peruvian liana, quinoa extract and carrot essential oil.[18]
- Fat Release: Releases existing fat cells, particularly with almond tree buds, rich in draining flavonoids, natural caffeine, immortelle, palmarosa and peppermint essential oils.[19]
- Slimming effectiveness clinically proven. ... 25 women after 28 days.[20]

The complaint further alleged: In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations ... at the time the representations were made. Therefore, the representation ... was, and is, false or misleading.[21]

The complaint also maintained that:

In truth and in fact:

A. Scientific tests do not prove that topical use of Almond Beautiful Shape trims 1.3 inches from the user's thighs in just four weeks;

B. scientific tests do not prove that topical use of Almond Beautiful Shape significantly reduces cellulite; and

C. scientific tests do not prove that Almond Shaping Delight significantly slims the body in just four weeks.[22]

Importantly, the complaint concluded:

Among other things, the evidence relied on by respondent for its representations concerning Almond Beautiful Shape consisted primarily of results from a single unblinded, uncontrolled clinical trial. Moreover, respondent exaggerated the results of the trial; the average reported reduction in thigh circumference was less than one-quarter of an inch, and only one participant out of 50 was reported to have achieved a reduction of 1.3 inches. ... Therefore, the representations ... were, and are, false or misleading.[23]

On March 27, 2014, the FTC issued a decision and order.[24] The decision acknowledges that:

The respondent, its attorney, and counsel for the FTC having thereafter executed an Agreement Containing Consent Order, which includes: a statement by respondent that it neither admits nor denies

any of the allegations in the draft complaint except as specifically stated in the consent agreement, and, only for purposes of this action, admits the facts necessary to establish jurisdiction; and waivers and other provisions as required by the commission's rules.”[25]

Many companies will opt, for a variety of reasons, not to litigate against the FTC. Thus, in situations like this, negotiation of and execution of consent orders are the general rule, not the exception.

The decision, among other things, requires that L’Occitane:

[I]n connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale or distribution of Almond Beautiful Shape, Almond Shaping Delight or any other topically applied product, in or affecting commerce, shall not represent, in any manner ... that use of such product causes substantial weight or fat loss or a substantial reduction in body size.[26]

The decision also requires that L’Occitane:

[S]hall, within 30 days after the date of entry of this order, provide to the FTC a searchable electronic file containing the name and contact information of all consumers who purchased Almond Beautiful Shape or Almond Shaping Delight from March 19, 2012, through the date of entry of this order ... including information available upon request from franchisees or others. Such file: (1) shall include each consumer's name and address, the product(s) purchased, the total amount of moneys paid less any amount credited for returns or refunds, the date(s) of purchase, and, if available, the consumer's telephone number and email address; (2) shall be updated through the National Change of Address database; and (3) shall be accompanied by a sworn affidavit attesting to its accuracy.[27]

L’Occitane was also ordered, to “pay to the Federal Trade Commission the sum of \$450,000.”[28]

Finally, the decision imposed administrative burdens on L’Occitane, including:

1. That L’Occitane shall deliver a copy of this order to all current and, for the next three years, all future principals, officers, directors and other employees having primary responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order ... ;[29] and
2. that L’Occitane, Inc., and its successors and assigns shall, within 60 days after the date of service of this order, file with the FTC a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order.[30]

As a result of the settlement, the FTC indicated its intent to mail “10,620 refund checks totaling more than \$416,000 ... to consumers who lost money buying two skin creams marketed by L’Occitane Inc., which falsely claimed the creams had ‘body slimming’ capabilities.”[31]

Conclusion

Because of tough competition it can be tempting for manufacturers to make drug-like claims for their cosmetic products. Making unsubstantiated drug claims,[32] however, can result in FDA warning letters, FTC complaints, increased regulatory burdens, fines and possibly consumer and shareholder law suits. All of these outcomes are undesirable and generally antithetical to increasing profits. Thus, when considering cosmetic claim wording, legal counsel should be consulted to minimize the possibility of triggering these unwanted events.

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[1] Revenue of the cosmetic industry in the U.S. from 2002 to 2016 (in billion U.S. dollars)", Statista — the Statistics Portal, 2015, available electronically here, last accessed March 28, 2015.

[2] See, e.g., 21 C.F.R § 720.4(c)(12).

[3] See 21 U.S.C. §§ 361-62.

[4] "The term 'cosmetic' means: (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, 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." 21 U.S.C. § 321(i).

[5] See, e.g., Sections 5(a) and 12 of the FTC Act.

[6] Cosmeceutical is a portmanteau of the terms cosmetic and pharmaceutical. The FDA does not recognize this classification of product. Rather, it regulates products that fall within the classification of drug or cosmetic, or combination products containing both a drug and a cosmetic. For combination products, the FDA will classify the product either as a cosmetic or a drug, for regulatory purposes.

[7] 21 U.S.C. § 361 defines adulterated:

A cosmetic shall be deemed to be adulterated —

(a) 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, except that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "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." and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid or decomposed substance.

(c) If it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of Section 379e (a) of this title.

[8] 21 U.S.C. § 362 defines misbranded:

A cosmetic shall be deemed to be misbranded —

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing:

(1) the name and place of business of the manufacturer, packer or distributor; and

(2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count: Provided, that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the secretary.

(c) If any word, statement or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed or filled as to be misleading.

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under Section 379e of this title. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of Section 361 (a) of this title).

(f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to Section 1472 or 1473 of Title 15.

[9] The Fair Packaging and Labeling Act, 16 C.F.R. Parts 500, 501, 502, 503, is also relevant to the analysis of labeling and misbranding.

[10] See 21 U.S.C. §§ 331-34.

[11] The FDA warning letter typically notes, e.g., that the claims indicate that these products are intended to affect the structure or any function of the human body, rendering them drugs under the FDCA. The marketing of these products with these claims evidencing these intended uses violates the FDCA. The FDA warning letter will also typically note e.g., that the cosmetics are not generally recognized among qualified experts as safe and effective for the above referenced uses and, therefore, the cosmetics are new drugs as defined in Section 201(p) of the FDCA. Under Section 505(a) of the FDCA, a new drug may not be legally marketed in the U.S. without prior approval from the FDA in the form of an approved new drug application.

[12] In the Matter of L'Occitane Inc., a corporation, Complaint, Docket No. C-4445, March 27, 2014 (Complaint), available electronically here, last accessed April 6, 2015.

[13] The complaint was issued on the same day as the FTC's decision and order, which is also discussed herein. The FTC's issuance of the complaint and decision and order were concluding steps in a process that included, among other things, negotiation and subsequent publication of a proposed consent order in the Federal Register, and a post-publication period for submission of public comments. See, e.g., 79 Fed. Reg. 2668 (2014).

[14] Complaint at page 2.

[15] Id.

[16] Id.

[17] Id. at page 3.

[18] Id.

[19] Id.

[20] Id. at page 4.

[21] Id.

[22] Id. at page 5.

[23] Id.

[24] In the Matter of L'Occitane Inc., a corporation, Decision and Order, Docket No. c-4445, March 27, 2014 (Decision), available electronically here, last accessed March 28, 2015.

[25] Decision at page 1.

[26] Id. at page 2.

[27] Id. at page 4.

[28] Id.

[29] Id. at page 6.

[30] Id.

[31] "FTC Sends Refund Checks Totaling More Than \$416,000 to Consumers Who Lost Money Buying "Body Slimming" Creams that Were Deceptively Marketed," FTC, March 20, 2015, available electronically at: <https://www.ftc.gov/news-events/press-releases/2015/03/ftc-sends-refund-checks-totaling-more-416000-consumers-who-lost>, last accessed April 6, 2015.

[32] Many cosmetics manufacturers make claims that they believe are substantiated. Problems typically arise when the cosmetics manufacturers and the FDA and FTC do not agree on the level of scientific evidence needed to support the claims.
