

**REMOVING THE WRINKLE IN COSMETICS
AND DRUG REGULATION: A NOTICE
RATING SYSTEM AND EDUCATION
PROPOSAL FOR ANTI-AGING
COSMECEUTICALS**

Victoria Farren

Anti-aging skincare products often make unrealistic anti-aging claims that mislead consumers, particularly older consumers. Because of the different premarket testing standards for cosmetics and drugs, companies often classify and market their anti-aging skincare products as cosmetics to the FDA in order to avoid more rigorous standards, yet simultaneously emphasize the drug-like qualities of the products to consumers, suggesting that these products are equivalent to drugs. The FDA allows these products, known as “cosmeceuticals,” to be classified as cosmetics despite their drug-like appearances and qualities, such as high-tech anti-aging skincare products that use nanotechnology, stem cell research, or DNA. The weakness of the present classification system in handling cosmeceuticals, which fall into the gray area between clearly defined cosmetics and drugs, creates unknown health risks and confuses and misleads consumers about the actual physiological effects of these products. To resolve these two problems, the Federal Food and Drug Administration need not extensively amend its regulations of the cosmetic and drug categories. Rather, the FDA should institute a notice system paired with consumer education, as well as more carefully regulate product claims.

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This Note is dedicated to the author’s mother and sister, “the two most beautiful women I know, with and without their cosmetics.”

I. Introduction

In 2005, Debra Scheufler, a forty-seven-year-old San Diego woman, filed a class action lawsuit against Estée Lauder and two department stores for false advertising in regards to anti-aging skincare cosmetics.¹ Scheufler had spent an estimated \$1000 on anti-aging skincare cosmetic products, including Estée Lauder's Crème de la Mer product, which retailed at \$120 per ounce at the time and was "touted by the website as a 'miracle' whose skin-enhancing ability 'defies the laws of nature.'"² "It didn't remove wrinkles or do anything to improve my skin," complained a disillusioned Scheufler, adding, "In fact, it clogged my pores and made my skin rougher."³ Scheufler is not alone in her confusion as an anti-aging skincare cosmetics consumer or in her decision to file suit against a cosmetics company over anti-aging skincare product claims.⁴

Hot on the heels of the increasing elderly population is the booming industry of anti-aging skincare products. One market research survey estimated sales of all skincare products in the United States racked up \$5.8 billion in 2006 alone, with \$7 billion projected by 2010.⁵ Among this growth, anti-aging skincare products lead the pack with double-digit growth rates and are hailed as "the fastest growing market segment across the globe."⁶ While baby boomers make up the core consumer market for anti-aging skincare products in the United

1. See NBC San Diego, *Woman Sues Estée Lauder for Not Making Her Look Younger*, NBCSANDIEGO.COM, Jan. 4, 2005 (on file with the Elder Law Journal at the University of Illinois); Sid Kirchheimer, *Scam Alert: Anti-Aging Snake Oil*, AARP BULL. TODAY, Nov. 2005, http://bulletin.aarp.org/yourmoney/scamalert/articles/scam_alert_anti-aging.html.

2. Kirchheimer, *supra* note 1.

3. *Id.*

4. See Simon Pitman, *Israel Lobby Group Files Class Action Against Cosmetic Players*, COSMETICSDSIGN.COM, June 20, 2007, <http://www.cosmeticsdesign.com/Products-Markets/Israel-lobby-group-files-class-action-against-cosmetics-players>.

5. Backchannelmedia, *Very Few Wrinkles in U.S. Skincare's Expected Growth to \$7 Billion by 2010!*, BACKCHANNELMEDIA, Jan. 3, 2007, <http://news.backchannelmedia.com/articles/7662/Very-Few-Wrinkles-in-US-Skincare-Expected-Growth-to-7-Billion-by-2010> [hereinafter *Very Few Wrinkles*].

6. Tom Branna, *Actives Speak Louder than Words*, HAPPY, June 13, 2006, <http://www.happy.com/articles/2006/06/actives-speak-louder-than-words> (comment made by Tom Goode, an executive from RITA Corporation). RITA provides chemical ingredients and research services to the cosmetics and personal care industries. See RITA CORP., GENERAL PRODUCT LISTING 1 (2006), available at http://www.ritacorp.com/files/Domestic_GPL.pdf.

States,⁷ this market is also expanding globally among aging populations in Japan and Western Europe.⁸

A trip to a department store or a browse through the Web sites of major cosmetics manufacturers reveals entire anti-aging skincare product lines.⁹ These cosmetics typically come with a price tag that is higher per volume than other cosmetic products by the same manufacturer.¹⁰ For example, Clinique's Repairwear Deep Wrinkle Concentrate for Face and Eye product can be purchased on Clinique's Web site for just over \$50 for one ounce.¹¹ In comparison to Clinique's other high-end special cosmetics, Super Defense Moisturizer, a lotion, and Redness Solutions, a cream to reduce rosacea, each retail around \$40 for 1.7 ounces, while Clinique's regular moisturizer, Dramatically Different Moisturizing Lotion, is \$11.50 for 1.7 ounces.¹² A sampling of other anti-aging products on the market include Estée Lauder's Perfectionist [CP+] product, advertised as a product to "dramatically reduce[] the appearance of lines, wrinkles and age spots."¹³ This "triumph over wrinkles" retails online for just over \$50 for one fluid ounce.¹⁴ Lancôme's High Resolution with Fibrelastine product, a self-proclaimed "intensive anti-wrinkle treatment," retails online at \$74 for

7. Natasha Singer, *Anti-Aging Makeup: Multitasker in a Jar*, N.Y. TIMES, Aug. 18, 2005, at G3.

8. See Branna, *supra* note 6.

9. Tex. Coop. Extension, Tex. A&M Univ. Sys., *Can Creams & Cosmetics Really Improve Aging Skin?*, in HEALTH HINTS 1, 1 (Janet M. Pollard & Carol A. Rice eds., 2005) [hereinafter *Creams & Cosmetics*].

10. See Clinique, Skin Care, Moisturizers, http://www.clinique.com/templates/products/multiproduct.tpl?category_id=category4918 (last visited Oct. 17, 2008) [hereinafter Clinique.com, Moisturizers].

11. Clinique, Repairwear Deep Wrinkle Concentrate for Face and Eyes, http://www.clinique.com/templates/products/sp_nonshaded.tpl?category_id=category4914&product_id=prod13047 (last visited Oct. 17, 2008).

12. Clinique.com, Moisturizers, *supra* note 10.

13. Estée Lauder, Perfectionist [CP+] with Poly-Collagen Peptides (on file with the Elder Law Journal at the University of Illinois).

14. See *id.* The Web site promotes the product as:

[y]our triumph over wrinkles. Not a single injection necessary. Estée Lauder Research boldly advances our most comprehensive anti-wrinkle treatment ever to prove just how far a skincare formula can go. The result? An anti-aging phenomenon with patent-pending triple enzyme technology and our exclusive Poly-Collagen Peptides. Perfectionist [CP+] "repairs" and corrects the look of lines, wrinkles and age spots faster than we ever have before.

Id.

1.7 fluid ounces.¹⁵ At Nordstrom's Web site, Yves Saint Laurent's "Age Expert" Age Defying Crème product, one ounce, can be purchased for \$88.¹⁶ Beyond the so-called prestige brands,¹⁷ local drug stores and supermarkets carry mass-market brands of anti-aging skincare products.¹⁸ Revlon has an Age Defying product line, including treatment, moisturizer, foundation, and concealer.¹⁹ Neutrogena offers an Anti-Oxidant Age Reverse product line including cleanser, lotion, eye cream, night cream, and serum.²⁰ Across the board in all price levels, anti-aging skincare products are widely available in the mass market.²¹

To meet the explosive demand for anti-aging skincare products, cosmetic companies are mixing new ingredients and new technology in a race to discover the secret to a youthful face.²² According to one source, the overall number of new cosmetic ingredients has more than doubled in the past twelve years.²³ Most new ingredients are referred

15. Lancôme, High Résolution with Fibrelastine, <http://www.lancome-usa.com/skincare/anti-aging/high-resolution-with-fibrelastine.htm> (last visited Oct. 17, 2008).

16. Nordstrom.com, Yves Saint Laurent "Age Expert" Age Defying Crème SPF 15, <http://shop.nordstrom.com/S/2822063> (last visited Oct. 17, 2008).

The cosmetic alternative to DHEA, Age Expert contains the ganoderic fraction—an exclusive active ingredient with a structure similar to the famous "hormone of youthfulness," capable of providing the epidermis with a reinvigorated look. It compensates for the signs of aging linked to hormonal imbalance, such as dull complexion, sagging skin and dehydration. Skin feels denser, softer and more radiant. The face looks visibly younger and is protected from environmental aggressions.

Id.

17. See Navin M. Geria, *Are High-Priced Cosmetics Really Worth the Price?*, HAPPI, Oct. 1, 2006, at 38 ("[P]restige brands include La Mer, Natura Bisse, Kanebo, La Prairie and ReVive."); *Creams & Cosmetics*, *supra* note 9, at 1.

18. See, e.g., Walgreens, Skin Care, <http://www.walgreens.com/beauty/skincare.jsp?CATID=304240> (last visited Oct. 17, 2008).

19. Revlon, Age Defying, <http://www.revlon.com/ProductCatalog/ProductLine.aspx?CollectionID=1> (last visited Oct. 17, 2008).

20. Neutrogena, Anti-Aging, <http://www.neutrogena.com/antiaging.asp?mainVal=antiaging&subVal=antiaging> (last visited Oct. 17, 2008).

21. See Tom Branna, *A New Era in Skin Care?*, HAPPI, Feb. 1, 2007, <http://www.happi.com/articles/2007/02/editors-page>. Procter & Gamble owns brands such as Olay, for mass market shoppers, and SK-II, for so-called prestige channels. See *id.*

22. See Vispi Kanga, *Novel Active Cosmetic Ingredient: Do Those Anti-Aging Cosmetics in Your Medicine Cabinet Do More Than Beautify the Skin?*, HAPPI, June 1, 2004, <http://www.happi.com/articles/2004/06/novel-active-cosmetic-ingredients>.

23. Branna, *supra* note 21 (stating that the number of cosmetic ingredients increased from 6200 in 1994 to 13,500 in 2006, a twelve-year span).

to by their scientific or chemical names, such as alpha-hydroxy acids (AHAs), beta-hydroxy acids, peptides, and retinoids.²⁴ Recent anti-aging skincare products also include some exotic natural ingredients, such as fermented sea kelp with specially cultivated algae, red arctic tocol cranberry, and “rare caviar extracts found only in the waters of the Caspian Sea from the roe of the beluga sturgeon during the natural birthing process.”²⁵ There is also “pietra,” created by a specific type of yeast, allegedly “accidentally discovered at a sake brewery when a monk noticed exceptional skin smoothness of a worker who had excessive wrinkles elsewhere on his body.”²⁶ New technologies applied to anti-aging skincare products include nanotechnology,²⁷ stem cell research,²⁸ and DNA technology.²⁹ The result of such an increase in ingredients with scientific names and new technology is a generation of cosmetics with an increasingly drug-like appearance and quality, often referred to as “cosmeceuticals.”³⁰ While cosmeceuticals may be any type of cosmetic, this Note will focus on anti-aging skincare cosmeceuticals.

Behind each new anti-aging skincare product is a truckload of anti-aging product claims. More than merely hiding wrinkles, diminishing age spots, and making skin appear firmer,³¹ products are now promising to prevent wrinkles and deliver “age-defying” results.³² One Estée Lauder advertisement for Re-Nutriv Ultimate Youth Crème suggests, “Imagine if you could postpone aging indefinitely.”³³ A Philosophy-brand face cream for preventing wrinkles is even named “Hope in a Jar.”³⁴ These marketing phrases and product claims suc-

24. Harvard Health Publ., *Skin Care and Repair*, AARP.ORG, Apr. 6, 2007, http://www.aarp.org/health/conditions/articles/harvard_skin-care-and-repair_0.html [hereinafter *Skin Care and Repair*].

25. See Geria, *supra* note 17, at 38.

26. See *id.*

27. See Robin Fretwell Wilson, *Nanotechnology: The Challenge of Regulating Known Unknowns*, 34 J.L. MED. & ETHICS 704, 706 (2006).

28. Judith Newman, *Stem-Cell Creams, DNA-Based Workouts, \$50,000 Check-ups*, VOGUE, Jan. 2007, at 193.

29. Branna, *supra* note 6 (discussing DNA as a possible skin repair tool).

30. See Bryan Liang & Kurt M. Hartman, *It's Only Skin Deep: FDA Regulation of Skin Care Cosmetics Claims*, 8 CORNELL J.L. & PUB. POL'Y 249, 261 (1999).

31. Branna, *supra* note 6 (providing study figures showing the global market for cosmetics and toiletries).

32. See NBC San Diego, *supra* note 1.

33. Estée Lauder, Re-Nutriv: Ultimate Youth Crème, http://esteelauder.com/templates/products/multiproduct.tmp?CATEGORY_ID=CATEGORY20223 (last visited Oct. 17, 2008).

34. Larissa Dubecki, *Peddling the Beauty Myth*, THE AGE, Oct. 14, 2006, at 3.

ceed by exploiting the fears and insecurities of aging consumers. As one writer describes, “baby boomers have both masterminded—and fallen victim to—an anti-aging epidemic far more virulent than the average case of mass hysteria.”³⁵

Selling the dream of youthfulness is not novel: products and treatments claiming anti-aging qualities have persisted throughout the ages. As far back as ancient Egypt, Cleopatra reportedly used sour milk high in lactic acid, which contained AHAs like those used in modern anti-aging skincare products, to give her skin a more youthful look.³⁶ However, there are two major concerns arising with this new wave of anti-aging skincare cosmeceutical products: the unknown potential for actual health risk and the increasing consumer confusion regarding the status of these products as either cosmetics or drugs.

First, current cosmetics and drug regulations keep a close watch over drugs, but leave cosmetics relatively unregulated.³⁷ Anti-aging skincare cosmeceuticals employing new ingredients and new technology are generally still considered to be cosmetics and, accordingly, are not required to undergo extensive premarket testing or meet other requirements.³⁸ As a result, relatively untested products may be sold to the mass market, leaving their unknown effects and interactions to be discovered later at the cost of unsuspecting consumers.³⁹

Second, aggressive anti-aging skincare product claims, in combination with the drug-like appearance of cosmeceuticals, are causing increased consumer confusion over the status of these products as cosmetics or drugs.⁴⁰ Everyone eventually faces the reality of time, but before doing so, a consumer may spend considerable amounts of money with distorted and unrealistic expectations, as was the case for Ms. Scheufler, whose cosmetic of choice was not unusually unique in its price tag.⁴¹ Some high-priced anti-aging skincare cosmetics in a 2006 study included La Mer brand Essence, which costs \$2100 for a

35. Susan Scarf Merrell, *Getting Over Getting Older*, PSYCHOL. TODAY, Dec. 1996, <http://psychologytoday.com/articles/pto-19961201-000026.html>.

36. Laura A. Heymann, *The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids*, 52 FOOD & DRUG L.J. 357, 359 (1997).

37. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., IS IT A COSMETIC, A DRUG, OR BOTH? (OR IS IT A SOAP?) (2002), <http://www.cfsan.fda.gov/~dms/cos-218.html> [hereinafter CFSAN, COSMETIC, DRUG, OR BOTH?].

38. *See id.*

39. Heymann, *supra* note 36, at 363.

40. *See* Geria, *supra* note 17, at 58.

41. *See* NBC San Diego, *supra* note 1.

three-week supply of cream,⁴² and DDF brand RMX, a \$1000, twenty-eight-day skincare regimen.⁴³

Cosmeceuticals, on the whole, have been a topic of concern since their first appearance on the mass market.⁴⁴ Categorized technically as cosmetics while appearing to cross into drug territory, classification of many of these new products does not conform satisfactorily with policy underlying existing cosmetic and drug regulations.⁴⁵ The existing cosmetic and drug system of regulation has been largely considered inefficient for handling cosmeceuticals.⁴⁶ In the context of anti-aging skincare cosmeceuticals, some suggested FDA reforms have included modifying existing drug and cosmetics categories, modifying tests to determine how products are classified, and adding a new cosmeceutical regulatory category.⁴⁷

In response to concerns over nanotechnology cosmeceuticals, the Food and Drug Administration (FDA) created the FDA Nanotech Task Force in August 2006 to determine a regulatory approach for products with nanotechnology materials.⁴⁸ However, focusing on a solution for one type of cosmeceutical at a time is merely dodging the tip of the iceberg. Nanotechnology is only one of many types of new technology being applied to cosmetics today.⁴⁹

Handling each problematic new cosmeceutical only after the negative health effects become apparent is both inefficient and risky. The best approach is one that not only solves the present situation, but may also be adapted to deal with increasingly high-tech future cosmeceuticals. In the case of anti-aging skincare cosmeceuticals, instead of modifying current regulatory categories or classification tests, the FDA should focus on a combination of alternative solutions to directly target the two concerns at hand. First, the risk of unknown side effects may be better allocated by providing consumers with notice through a notice system. Second, consumer confusion is best handled

42. Geria, *supra* note 17, at 38.

43. *Id.*

44. Liang & Hartman, *supra* note 30, at 262.

45. *Id.* at 262–63.

46. *See id.*; Heymann, *supra* note 36, at 371–72.

47. *See* Heymann, *supra* note 36, at 373–74.

48. NANOTECHNOLOGY TASK FORCE, U.S. FOOD & DRUG ADMIN., NANOTECHNOLOGY 5 (2007), available at <http://www.fda.gov/nanotechnology/taskforce/report2007.pdf> [hereinafter FDA, NANOTECHNOLOGY].

49. *See id.* at 4–6.

by better education for the public and stricter policing of anti-aging product claims.

This Note responds specifically to the growing industry of anti-aging skincare cosmeceuticals, but the solution may be expanded to other cosmeceuticals as well. Part II examines the current cosmetic and drug classifications and the appearance of cosmeceuticals. Part III discusses the problems of the current system in light of emerging anti-aging skincare cosmeceuticals. Part IV proposes a two-part recommendation that does not alter the present FDA classification system.

II. Background

A. Cosmetic and Drug Regulation

Exactly what is a cosmetic and what is a drug? Either may be a product topically applied to the body.⁵⁰ Either may consist of compositions ranging from naturally occurring raw substances to manmade chemical compounds to any combination thereof.⁵¹ Congress defined both terms in the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).⁵² Section 201(i) of the FDCA defines *cosmetic* as a product, not including soap, “intended to be rubbed, poured, sprinkled, or sprayed on, introduced to, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness or altering the appearance.”⁵³ In comparison, section 201(g) defines *drug* to include, among other things, “articles intended for use in the diagnosis, 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.”⁵⁴ As per court decisions and legislative history, the legal definition of the term *intended* with respect to the use of a product means the desired or prescribed use as determined by statements on the product’s labeling.⁵⁵ In short, cosmetics

50. See CFSAN, COSMETIC, DRUG, OR BOTH?, *supra* note 37.

51. See, e.g., Vispi Kanga, *Sophisticated Cosmetic Ingredients*, HAPPI, June 1, 2005, <http://www.happi.com/articles/2005/06/sophisticated-cosmetic-ingredients>.

52. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321(g)(1), (i) (2000).

53. § 321(i).

54. § 321(g)(1).

55. *United States v. An Article*, 409 F.2d 734, 739 (2d Cir. 1969) (noting that “it is well settled that the intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant source” and listing cases); S. REP. NO. 74-361 (1935); Jacqueline A. Greff, *Regulation*

are products intended to exert a physical effect on the body; drugs are products intended to exert a physiological effect on the body.⁵⁶ A product may legally be a combination of the two if it is intended to exert both a physical and physiological effect.⁵⁷

Congress designated the FDA, under the Department of Health and Human Services, as the authorized agency responsible for regulating cosmetics and drugs under the FDCA.⁵⁸ The FDA, in turn, has created two sets of regulatory standards based on the categorization of a product as a cosmetic or a drug in the statute.⁵⁹ Drug regulation is considerably more extensive than cosmetic regulation.⁶⁰ Important differences between the two regimes are present in the areas of approval requirements, good manufacturing practices, registration, and labeling.⁶¹ First, drugs are generally subject to premarket approval by the FDA, or they must conform to certain final regulations.⁶² In contrast, the FDA does not have a premarket approval system for cosmetics, with an exception for color additives and certain prohibited ingredients.⁶³ Second, drugs must strictly adhere to specific good manufacturing practice (GMP) requirements and certain minimum standards.⁶⁴ Failure to conform to GMP requirements may cause a drug to be considered adulterated.⁶⁵ No regulations set forth specific

of Cosmetics That Are Also Drugs, 51 FOOD & DRUG L.J. 243, 253–54 (1996); *see also* Kanga, *supra* note 22, at 61.

56. Kanga, *supra* note 22, at 61.

57. *Id.*

58. Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., Time Line, <http://www.fda.gov/cder/about/history/time1.htm> (last visited Oct. 17, 2008).

59. CFSAN, COSMETIC, DRUG, OR BOTH?, *supra* note 37. The Center for Food Safety and Applied Nutrition (CFSAN) is one of the five major centers under the FDA organization. *See* Compliance Home, FDA Resources, <http://www.compliancehome.com/topics/FDA> (last visited Oct. 17, 2008).

60. Heymann, *supra* note 36, at 363–64; CFSAN, COSMETIC, DRUG, OR BOTH?, *supra* note 37.

61. CFSAN, COSMETIC, DRUG, OR BOTH?, *supra* note 37.

62. *Id.*

63. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., INGREDIENTS PROHIBITED AND RESTRICTED BY FDA REGULATIONS (2006), <http://www.cfsan.fda.gov/~dms/cos-210.html>.

64. CFSAN, COSMETIC, DRUG, OR BOTH?, *supra* note 37 (citing current minimum GMP requirements for drugs at 21 C.F.R. pts. 210–11 (2008)).

65. *Id.*

A drug or device shall be deemed to be adulterated . . . if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the require-

GMP requirements for cosmetics.⁶⁶ Third, drug firms must register establishments and list drug products with the FDA.⁶⁷ Cosmetic establishments and formulations may be voluntarily registered through the Voluntary Cosmetic Registration Program.⁶⁸ According to the FDA's Office of Cosmetics and Colors, only about 35% to 40% of cosmetics manufacturers participate in the program.⁶⁹ Fourth, label requirements for cosmetics are found in the Cosmetic Labeling Manual.⁷⁰ Cosmetic labels may list active and other ingredients together in order of predominance.⁷¹ Over-the-counter (OTC) nonprescription drugs are labeled according to OTC drug regulations, which require ingredient lists and specifically distinguish between "active" and "inactive" ingredients.⁷² If a product qualifies as both an OTC drug and a cosmetic, then it must meet the combination OTC drug and cosmetic labeling requirements.⁷³ For example, antidandruff treatment shampoo must comply with both requirements—it is a cosmetic, because it is used to cleanse, and also a drug, because it is used to treat dandruff by affecting the follicles where the hair is formed.⁷⁴

B. Cosmeceuticals and Anti-Aging Products

Today, the challenge is how to reconcile the FDCA's cosmetic and drug definitions with modern cosmeceuticals. Cosmetic regulations have changed little since the passage of the FDCA in 1938.⁷⁵ Yet

ments of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 351 (2000).

66. CFSAN, COSMETIC, DRUG, OR BOTH?, *supra* note 37.

67. *Id.* (citing Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360, and 21 C.F.R. § 207).

68. *Id.* (citing 21 C.F.R. §§ 710, 720).

69. Carol Lewis, *Clearing Up Cosmetic Confusion*, FDA CONSUMER, May–June 1998, http://www.fda.gov/fdac/features/1998/398_cosm.html.

70. See CFSAN, COSMETIC, DRUG, OR BOTH?, *supra* note 37; CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., COSMETIC LABELING MANUAL (1991), <http://www.cfsan.fda.gov/~dms/cos-lab1.html> [hereinafter COSMETIC LABELING MANUAL].

71. See COSMETIC LABELING MANUAL, *supra* note 70 (discussing the Declaration of Ingredients).

72. CFSAN, COSMETIC, DRUG, OR BOTH?, *supra* note 37 (OTC drug labeling includes the "Drug Facts" labeling, as described in 21 C.F.R. § 201.63).

73. *Id.* ("For example, the drug ingredients must be listed alphabetically as 'Active Ingredients,' followed by cosmetic ingredients, listed in order of predominance as 'Inactive Ingredients.'").

74. See *id.*

75. See Greff, *supra* note 55, at 244–45.

applying new developments in science and technology to cosmetics has spawned a new generation of personal care products that appear to fall into the gray area between the cosmetics and drugs categories.⁷⁶ These cosmetic products with drug-like effects have become so common that they are now frequently referred to as “cosmeceuticals.”⁷⁷

While the market growth for skincare cosmeceuticals has been in the double and triple digits in recent years,⁷⁸ the term *cosmeceuticals* is not officially recognized by the FDA and has no meaning under law.⁷⁹ Instead, products known as cosmeceuticals fall under one or both of cosmetic and drug categories.⁸⁰ For these products, often no more than a fine line exists between cosmetic and drug classification.⁸¹ For example, animal estrogen added to skin creams or lotions results in the product being classified as a drug, while the addition of phytoestrogen, with similar effects as animal estrogen but created from plants, does not change the classification to drug.⁸² Tretinoin (retinoic acid), a biologically active form of vitamin A found in antiwrinkle cosmetics, is recognized as a drug when used topically to treat certain skin conditions.⁸³

Anti-aging skincare products, fueled by an expanding aging population, lead the rapid growth of skincare product sales in the United States.⁸⁴ These anti-aging skincare products generally claim to reduce the appearance of aging by changing the appearance of wrinkles, particularly on the face.⁸⁵ Wrinkles are the visible result of deterioration in fibers of the dermis, the layer of tissue beneath the epidermis, the outer layer of skin.⁸⁶ Two important components of the skin, collagen and elastin, are affected.⁸⁷ Damage may come as a re-

76. See Kanga, *supra* note 22.

77. Tex. Coop. Extension, Tex. A&M Univ. Sys., *Drug, Cosmetic, or Both? . . . “Cosmeceuticals”?*, in HEALTH HINTS, *supra* note 9, at 3, 3.

78. LaToyah Burke, *Advances in Skin Care*, HAPPI, Dec. 1, 2006, <http://www.happi.com/articles/2006/12/advances-in-skin-care>.

79. CFSAN, *COSMETIC, DRUG, OR BOTH?*, *supra* note 37.

80. See *id.*

81. See Kanga, *supra* note 22.

82. *Id.*

83. Carol Rados, *Science Meets Beauty: Using Medicine to Improve Appearances*, FDA CONSUMER, Mar.–Apr. 2004, http://www.fda.gov/fdac/features/2004/204_beauty.html. Tretinoin is considered a drug when used to treat certain skin conditions because it acts deep at the skin’s cellular level to increase collagen. *Id.*

84. See *Very Few Wrinkles*, *supra* note 5.

85. See Rados, *supra* note 83.

86. See *id.*

87. See *id.*

sult of gravity, ultraviolet sun damage, pollution, exposure to smoke or chemicals, and other sources.⁸⁸ One accelerator of the aging process is the presence of free radicals that cause skin damage.⁸⁹ Free radicals may be removed by antioxidants, which are naturally in short supply in aging skin.⁹⁰

While many anti-aging skincare products merely hide wrinkles, many new products seek to actually reduce and prevent wrinkles.⁹¹ Some function by delivering antioxidants, amino acids, proteins, and the like to the skin.⁹² Others function by boosting the skin's natural production of antioxidants.⁹³ Some cosmetics focus on collagen and elastin production in the skin.⁹⁴ Many new anti-aging skincare cosmetics that do more than merely cover up and hide wrinkles approach the drug regulatory lines and thus enter into cosmeceutical territory. These particular anti-aging cosmeceuticals primarily impact elderly consumers.

III. The Problems of the Inadequate Current System

The emerging pool of anti-aging skincare cosmeceuticals fits awkwardly with current FDA cosmetic and drug regulations because many products fall through the cracks of the policy concerns that underlie the classification. This Part will examine two major concerns: unknown health risks and consumer confusion.

A. Unknown Health Risks

FDA regulations exist for the purpose of protecting public health.⁹⁵ Congress enacted the FDCA partially in response to the

88. *Id.*; Tex. Coop. Extension, Tex. A&M Univ. Sys., *Aging Skin 101*, in HEALTH HINTS, *supra* note 9, at 5, 5 [hereinafter *Aging Skin 101*].

89. *Aging Skin 101*, *supra* note 88, at 5.

90. *Id.*

91. See Rados, *supra* note 83.

92. See Geria, *supra* note 17, at 38.

93. See *id.*

94. See *id.*

95. U.S. Food & Drug Admin., FDA's Mission Statement, <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Oct. 17, 2008).

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable;

many horror stories of consumers who were crippled or poisoned by unregulated cosmetic products in the early 1900s.⁹⁶ Such stories include the famous Lash Lure case, where a woman used an eyelash dye with an ingredient, Kormelu, containing rat poison.⁹⁷ After an evening of itching and burning, she awoke the next morning to find “her eyes [were] gone and the flesh around them [was] a mass of tortured scars.”⁹⁸

Cosmetic and drug regulations protect public health by setting up requirements and monitoring for potentially dangerous products on the market.⁹⁹ Drugs are assumed to be inherently risky and are thus subject to pervasive regulation to ensure safety and efficacy.¹⁰⁰ Drug manufacturers are generally required to perform extensive testing and obtain premarket approval before selling products to the public.¹⁰¹ Simultaneously, Congress balances safety with a competing policy to avoid implementing burdensome regulations unless there is clear need.¹⁰² Thus, cosmetics, which are viewed as very low risk to consumer health, receive comparatively broad freedom from regulation outside of specifically banned ingredients.¹⁰³

In the race to meet the high demand for anti-aging skincare products, cosmetic companies are creating more and more anti-aging skincare cosmeceuticals.¹⁰⁴ These new cosmeceuticals carry a stronger risk for unknown side effects because of the relative newness of certain ingredients and technology used.¹⁰⁵ However, despite the increased safety risk, they are typically classified as cosmetics and thus

and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

Id.

96. See Erika Kawalek, *Artfully Made-Up*, LEGAL AFFAIRS, Nov.–Dec. 2005, http://www.legalaffairs.org/issues/November-December-2005/feature_kawalek_novdec05.msp.

97. GWEN KAY, DYING TO BE BEAUTIFUL 5 (Susan L. Smith & Nancy Tomes eds., 2005); Kawalek, *supra* note 96.

98. Kawalek, *supra* note 96.

99. See CFSAN, COSMETIC, DRUG, OR BOTH?, *supra* note 37.

100. See Greff, *supra* note 55, at 250.

101. Heymann, *supra* note 36, at 363–64; CFSAN, COSMETIC, DRUG, OR BOTH?, *supra* note 37.

102. Greff, *supra* note 55, at 250.

103. Heymann, *supra* note 36, at 364; Kawalek, *supra* note 96.

104. Melissa Meisel, *The Doctor's Orders: Professional Skin Treatments Complement Spa Services*, HAPPI, Dec. 1, 2007, <http://www.happi.com/articles/2007/12/the-doctors-orders>.

105. See Lewis, *supra* note 69.

enjoy a low regulation standard.¹⁰⁶ Cosmetics are not required to have expansive testing or premarket approval before being sold to the mass market.¹⁰⁷ While cosmetics manufacturers necessarily perform some testing, many risks of new cosmeceuticals are passed on to the mass consumer.¹⁰⁸ Many consumers purchase cosmetic products assuming they are safe to use and do not consider the possible risks and side effects of those products.¹⁰⁹ In contrast, when consumers purchase drugs, they are more likely to read the warning labels and consider the dangers of side effects and interactions.¹¹⁰ In this way, the unsuspecting consumers bear the unknown health risks of new cosmeceuticals.¹¹¹ For anti-aging skincare cosmeceuticals, an aging group of consumers bears the risks. This section examines the case of anti-aging skincare cosmeceuticals containing AHAs and the parallels that may be drawn to new anti-aging skincare cosmeceuticals implementing nanotechnology.

1. ALPHA-HYDROXY ACIDS

The shortcomings of the current regulatory system in managing new cosmeceuticals are exemplified by the case of alpha-hydroxy acids,¹¹² considered in the 1990s to be the centerpiece of emerging cosmeceuticals.¹¹³ AHAs are a type of acid found in ingredients including glycolic, lactic, citric, malic, mandelic, and tartaric acids.¹¹⁴ AHAs are “basically chemical versions of facial scrubs.”¹¹⁵ AHAs typically exfoliate the top layer of skin to expose the fresher-looking skin underneath.¹¹⁶ Essentially, the use of this ingredient allows consumers to use milder cosmetic versions of chemical peels at home.¹¹⁷

106. See CFSAN, COSMETIC, DRUG, OR BOTH?, *supra* note 37.

107. See *id.*

108. See Kawalek, *supra* note 96.

109. See *id.* “An April 2004 survey conducted by the National Consumers League revealed that 6 out of 10 adults think that the FDA tests anti-aging products for safety and efficacy. It does no such thing.” *Id.*

110. See Kathleen Doheny, *Good Karma*, L.A. TIMES, Jan. 2, 2002, at 1.

111. See Env'tl. Working Group, *FDA Fails to Protect Consumers*, SKIN DEEP, Oct. 5, 2005, <http://www.cosmeticdatabase.com/research/fdafails.php?nothanks=1>.

112. Heymann, *supra* note 36, at 358.

113. *Id.* CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FOOD & DRUG ADMIN., ALPHA HYDROXY ACIDS FOR SKIN CARE (1999), <http://www.cfsan.fda.gov/~dms/fdacaha.html>.

114. Heymann, *supra* note 36, at 358.

115. Liang & Hartman, *supra* note 30, at 265.

116. Heymann, *supra* note 36, at 357.

117. Paula Kurtzweil, *Alpha Hydroxy Acids for Skin Care*, FDA CONSUMER, May 1998, <http://www.foodsafety.gov/~dms/fdacaha.html>.

From 1992, AHAs began appearing in products on the mass market and quickly became popular.¹¹⁸ Hailed as the new “elixir of youth,” AHAs took the market by storm.¹¹⁹ Products containing AHAs were typically categorized as cosmetics, thus avoiding premarket testing requirements.¹²⁰ These products varied widely from cuticle softeners to shampoos, but AHAs were included most notably in skincare products such as face creams and lotions.¹²¹ The products were available everywhere from discount pharmacies to department stores in products that ranged broadly in price.¹²²

Widespread product availability occurred before the side effects and health risks of AHAs were fully known.¹²³ By 1998, John Bailey, the acting director of the FDA’s Office of Cosmetics and Colors, estimated that approximately 10,000 adverse reactions were received from products containing AHAs.¹²⁴ Bailey further commented that “AHAs are unlike anything else ever introduced onto the cosmetic market on such a wide scale. They are not your traditional cosmetics.”¹²⁵ Complaints received by the FDA included severe redness, swelling (especially in the area of the eyes), burning, blistering, bleeding, rash, itching, and skin discoloration.¹²⁶ In a 1996 study conducted by the Office of Cosmetics and Colors, AHAs were found to “drastically alter the structure of the skin, inducing as much as a four-fold increase in the thickness of the epidermis, the top layer of the skin.”¹²⁷ Another study by the Cosmetic Ingredient Review, an independent review panel established by the Cosmetic, Toiletry, and Fragrance Association (CTFA), demonstrated that topically applied AHAs result in an increased skin sensitivity to ultraviolet radiation, which may remain for a week after discontinuing application.¹²⁸ The increased skin

118. See Heymann, *supra* note 36, at 357; Kurtzweil, *supra* note 117.

119. Heymann, *supra* note 36, at 357–58.

120. *Id.* at 363.

121. Kurtzweil, *supra* note 117.

122. *Id.* Some AHAs, including glycolic acid and lactic acid, can be found in face and body creams and lotions, some shampoos, and cuticle softeners. *Id.*

123. See, e.g., *id.*

124. *Id.* The FDA received more than 100 reports of adverse reactions; however, for each adverse reaction report received by the FDA, the manufacturers receive fifty to 100. *Id.* “This would translate into approximately 10,000 adverse reactions being received for AHA-containing products.” *Id.*

125. *Id.*

126. *Id.*

127. Heymann, *supra* note 36, at 360.

128. See CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FOOD & DRUG ADMIN., LABELING FOR TOPICALLY APPLIED COSMETIC PRODUCTS CONTAINING ALPHA

sensitivity also makes consumers more susceptible to sunburn.¹²⁹ In 2000, the CTFA submitted a citizen petition requesting that the FDA establish label requirements for cosmetic products with AHAs to notify consumers of the risk of increased skin sensitivity to the sun.¹³⁰ The petition further noted that products containing AHAs represented a significant portion of the \$6 billion domestic skincare market at the time.¹³¹

In 2005, after AHAs had been widely available on the mass market for well over a decade, the FDA finally responded by issuing a recommended “sunburn alert” warning to be added as a labeling statement for cosmetic products containing AHAs as ingredients.¹³² This warning is only in response to the short-term effects of AHAs; at the time of the sunburn alert issuance, the FDA’s National Center for Toxicological Research was still investigating long-term exposure.¹³³

While the risk of AHAs has now been investigated¹³⁴ and recommended safety concentrations and acidity levels for AHAs are now known,¹³⁵ the first widespread skincare products containing AHAs were released before this knowledge was acquired.¹³⁶ There is no guarantee the next new ingredient or future technology will have similar, relatively benign effects.¹³⁷ If the next cosmeceutical on the

HYDROXY ACIDS AS INGREDIENTS (2005), <http://www.cfsan.fda.gov/~dms/ahaguid2.html> [hereinafter CFSAN, LABELING].

129. Kurtzweil, *supra* note 117.

130. CFSAN, LABELING, *supra* note 128 (citizen petition dated June 29, 2000, assigned FDA Docket No. 2000P-1378/CP1).

131. *Id.*

132. *Id.* The FDA encourages manufacturers to use the following recommended labeling statement for cosmetic products containing AHAs as ingredients: “Sunburn Alert: This product contains an alpha hydroxyl acid (AHA) that may increase your skin’s sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for a week afterwards.” *Id.*

133. *Id.*

134. *See id.* The Cosmetic Ingredient Review (CIR) released an independent report regarding safe levels of AHAs for consumers. Tex. Coop. Extension, Tex. A&M Univ. Sys., *Hydroxy Acids*, in HEALTH HINTS, *supra* note 9, at 8, 8 [hereinafter *Hydroxy Acids*].

135. Jane E. Brody, *Time to Review Your Cosmetics, Under Bright Light*, N.Y. TIMES, May 22, 2001, at F5. An industry review found AHAs safe to use at concentrations of 10% or less, with a final product that has an acidity level no lower than pH 3.5. *Id.*

136. *See* CFSAN, LABELING, *supra* note 128. Since January 2005, the FDA has had guidelines for labeling products containing AHAs to alert consumers about sun sensitivity. *See id.*; *Hydroxy Acids*, *supra* note 134, at 9.

137. *See* CFSAN, LABELING, *supra* note 128 (using products with AHA can lead to skin sensitivity or sunburn).

market is found to be a high health risk, the time lag in the current system effectively leaves mass consumers to be unsuspecting guinea pigs.

2. NANOTECHNOLOGY

In a parallel to AHAs, nanoscience-based anti-aging skin care is a new type of cosmeceutical growing in popularity and availability on the mass market despite unknown health risks.¹³⁸ Nanotechnology involves the production and use of materials with nanosized particles (NSPs).¹³⁹ One nanometer is one billionth of a meter and invisible to the naked eye.¹⁴⁰ NSPs are increasingly being used as a way to manipulate matter at a molecular level to change the characteristics of materials.¹⁴¹ For example, a golf club head employing nanosized carbon allotrope resists bending significantly more than conventional clubs, thus leading to improved ball flight.¹⁴² Certain textiles have been made using nanotechnology to be allegedly “extremely resistant to wrinkles and most stains” compared to the same textiles without nanotechnology.¹⁴³

In 2005, the FDA was quoted admitting “very little is known about the interaction of nano-scale particles and the skin.”¹⁴⁴ Recent hazard assessments have also determined that the “impacts of nanomaterials on human health and the environment remain largely speculative.”¹⁴⁵ Despite this, the use of NSPs has been found in over thirty new anti-aging skincare cosmetics.¹⁴⁶ For example, L’Oréal, the world’s largest cosmetics company, has a product, Revitalift, containing nanosomes of Pro-Retinol A.¹⁴⁷ Lancôme Hydra Zen and some

138. See Darla Martin Tucker, *Nanotech Puts New Wrinkle in Skin Care*, BUS. PRESS, May 7, 2006, http://www.thebizpress.com/profiles/stories/BP_News_Local_D_bp60508_profile.1006bd83.html. Beyond Skin Science company has been selling a full line of nanoscience-based anti-aging products since 2004. *Id.*

139. Wilson, *supra* note 27, at 704.

140. *Id.*

141. *Id.* at 705.

142. *See id.*

143. *Id.*

144. Lois Rogers, *Safety Fears over ‘Nano’ Anti-Aging Cosmetics*, SUNDAY TIMES, July 17, 2005, <http://www.timesonline.co.uk/tol/news/uk/article544891.ece>.

145. Wilson, *supra* note 27, at 705.

146. *Id.* at 706–07.

147. Rogers, *supra* note 144. L’Oréal RevitaLift Double Lifting antiwrinkle cream, already available at drugstores, has a product label that includes the text, “Pro-Tensium plus nanosomes of Pro-Retinol A.” Nell Greenfieldboyce, *Safety of Nano-Cosmetics Questioned* (National Public Radio Broadcast Mar. 13, 2006) (tran-

Olay lotions also contain NSPs.¹⁴⁸ Estée Lauder and Johnson & Johnson are both developing products based on nanotechnology.¹⁴⁹ NSPs are not limited to anti-aging products either; other cosmetics on the market, including sunscreens and exfoliating products, contain NSPs.¹⁵⁰

The concern over the dangers of nanoscience cosmetics revolves around several issues. First, the properties of substances change at the nano size, so NSPs should be evaluated differently from their bulk counterparts.¹⁵¹ For example, under normal or bulk conditions, gold is yellow and inert.¹⁵² However, in a nanoscale size, gold becomes blue with low reactivity.¹⁵³ Shrunk even further, it becomes reddish and catalytic.¹⁵⁴ Therefore, in the case of cosmetics with NSPs, an ingredient list may appear the same as the traditional cosmetic while the level of risk may change.¹⁵⁵ Studies suggest nano-sized materials are “not inherently benign and that they affect biological behaviors at the cellular, subcellular and protein levels.”¹⁵⁶

Second, the small size of an NSP allows the particle to penetrate barriers that the bulk-size version of the same ingredient cannot.¹⁵⁷ The topical application of NSPs includes the risk that particles may penetrate the skin and move around the body unpredictably.¹⁵⁸ NSPs may penetrate cells, enter the blood supply, and cross the blood-brain barrier.¹⁵⁹ Some cosmetics use lipid nanosomes as “delivery systems for controlled release of active ingredients.”¹⁶⁰ Before selling products

script available at <http://www.npr.org/templates/story/story.php?storyId=5257306>).

148. See Wilson, *supra* note 27, at 706; Greenfieldboyce, *supra* note 147.

149. See Rogers, *supra* note 144.

150. See *Consumer Groups Urge More Regulation, Testing for Nanotechnology Products*, in 11-20 MEALEY'S EMERGING DRUGS & DEVICES 21 (2006) [hereinafter MEALEY'S]; Press Release, Klein-Becker, This Year It's All About Hands! (Oct. 23, 2006), http://www.tfwa.com/duty_free/uploads/media/06_10_23_kb_.pdf (introducing a new nano product employing “thermo-active nanoexfoliating technology”).

151. See MEALEY'S, *supra* note 150.

152. *Id.*

153. *Id.*

154. *Id.*

155. See Env'tl. Working Group, *Nanotechnology, SKIN DEEP*, http://www.cosmeticdatabase.com/special/sunscreens2008/report_nanotechnology.php (last visited Oct. 17, 2008).

156. Wilson, *supra* note 27, at 706.

157. See *id.* at 709.

158. See *id.*

159. See *id.*; MEALEY'S, *supra* note 150.

160. Wilson, *supra* note 27, at 706.

applying nanotechnology to cosmetics, researchers should examine NSP interaction with DNA, the extent to which they penetrate the skin, where they go in the body, and whether they are toxic.¹⁶¹ Although the body has mechanisms for clearing out foreign substances, NSPs are harder for the body to dispose of because of their small size.¹⁶²

Despite these additional risks, new cosmetics on the market employing NSPs are not required to undergo special testing or premarket screening, and the FDA has no authority to directly recall cosmetics found to be harmful to consumers.¹⁶³ As stated by the FDA's Center for Drug Evaluation and Research, "currently there are no testing requirements that are specific to nanotechnology products."¹⁶⁴ In 2006, eight health, environmental, and consumer groups petitioned the FDA to amend regulations to define nanotechnology and treat products with NSPs as new substances.¹⁶⁵ Since then, the FDA Nanotech Task Force has released a report expressing concern over nanotechnology products not subject to premarket testing.¹⁶⁶ The Royal Society, the United Kingdom's national academy of science, has also expressed concern about NSPs in anti-aging skincare cosmetics and their unknown long-term effects.¹⁶⁷

In addition, a new generation of cosmeceuticals are on the horizon. One new type of cosmetic treatment under investigation, originally developed to treat burn victims by scientists in Russia, involves stem-cell technology and fat injections to reduce wrinkles.¹⁶⁸ Other

161. MEALEY'S, *supra* note 150 (discussing nanotechnology and cosmetics safety concerns of Dr. Philippe Martin of the European Commission and others).

162. *See* Wilson, *supra* note 27, at 709 (discussing tests done on rats exposed to NSPs and micrometer-sized particles).

163. *See id.* at 708.

164. *Id.* (citing NAKISSA SADRIEH, FDA CONSIDERATIONS FOR REGULATION OF NANOMATERIAL CONTAINING PRODUCTS (2006), http://www.fda.gov/nanotechnology/NIST_meeting_Houston_01-06.ppt#38).

165. *See id.* (discussing the "Citizen Petition to the United States Food and Drug Administration," available at <http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf>). "The petitioners want the FDA to amend its regulations to define nanotechnology, promulgate new regulations under which nano products would be treated as new substances." *Id.*

166. *See* FDA, NANOTECHNOLOGY, *supra* note 48, at 5.

167. *See* Rogers, *supra* note 144.

168. *See* Newman, *supra* note 28, at 193 ("In Europe, a lot of the stem-cell injections for skin rejuvenation are human embryonic—from tissue from abortions, for example, or unwanted embryos—though it's not talked about."); *see also* Dan Childs, *Stem Cells for Beauty?*, ABC NEWS, Nov. 24, 2006, <http://abcnews.go.com/Health/Cosmetic/story?id=2674304&page=1> (discussing future stem cell applications in cosmetics).

new cosmetics focus on DNA for anti-aging serums and creams¹⁶⁹ and the use of human growth hormone.¹⁷⁰ Yet another new product is a gel containing a 3% extract of a neurotransmitter, a substance produced in the brain, to reduce forehead frown lines and tighten sagging neck skin.¹⁷¹ As with nanotechnology, the health effects of these products are largely unknown.¹⁷² While nanotechnology involves a different set of risks from AHAs, the parallel remains in that new cosmetics are being sold to consumers who are largely unaware of the risks involved.¹⁷³ Negative side effects will likely be discovered by the mass consumers, primarily consisting of an aging population. A more effective system should be implemented to handle new cosmeceuticals before adverse events occur. The AHA warning label and Nanotech Task Force are fixes that are specific to certain cosmeceuticals.¹⁷⁴ Ultimately, they are a temporary Band-Aid to make up for deficiencies in the system until the next generation of cosmeceutical is developed.¹⁷⁵

B. Consumer Confusion

There is increasing consumer confusion regarding the status of anti-aging skincare cosmeceutical products as cosmetics instead of drugs, while the products themselves generally do not actually qualify as drugs under the FDA's regulations. A member of the NPD Group, a market research company, commented,

[W]e don't necessarily see a shift in focus from traditional dermatology to cosmeceuticals. What we've seen is that traditional dermatology and the trust that consumers hold in doctors and medicine has launched cosmeceutical skin care into super stardom.

169. See Burke, *supra* note 78 (the DNA Repair Formula is an anti-aging serum that treats photo damage and environmental stress); Simon Pitman, *DNA-Tested Cosmetics Come to Europe*, COSMETICSDSIGN-EUROPE.COM, July 27, 2006, <http://www.cosmeticsdesign-europe.com/news/ng.asp?n=69441-genelink-dermagenetics-dna-anti-ageing>. Genelink's Dermagenetics brand creates a face cream in a lab according to a DNA swab taken from the customer. *Id.*

170. See Vispi Kanga, *Sophisticated Cosmetics Ingredients*, HAPPI, June 1, 2005, <http://www.happi.com/articles/2005/06/sophisticated-cosmetic-ingredients>. The Nanolipo-hGH Retinol Plus product by Regeron, a Korean company, designed for enhanced antiwrinkle treatment, uses a raw material that is a bioactive human growth hormone stabilized in nano-sized liposomes for use in cosmetics. *See id.*

171. *Skin Care and Repair*, *supra* note 24.

172. Heymann, *supra* note 36, at 359-60.

173. *Id.*

174. See CFSAN, LABELING, *supra* note 128; FDA, NANOTECHNOLOGY, *supra* note 48.

175. See FDA, NANOTECHNOLOGY, *supra* note 48.

Because cosmeceuticals are associated with doctors and medicine, consumers hold more belief in the efficacy and potency of these products to actually deliver on their promises.¹⁷⁶

The results of this are disappointed consumers who believed the cosmetics would work as drugs and their subsequent lawsuits.¹⁷⁷ The change in consumer perception is largely caused by a combination of misleading anti-aging product claims and an increasingly drug-like appearance of new products.¹⁷⁸

New anti-aging skincare cosmeceuticals have increasingly potent product claims.¹⁷⁹ Rather than simply hiding imperfections, products are claiming to fight them.¹⁸⁰ The cosmetics industry sells an image and leaves the consumer to believe the claims or not, but many consumers do not realize this.¹⁸¹ Surveys have found that consumers generally believe cosmetic claims and expect products to actually prevent or slow the formation of wrinkles if such a claim is made on the packaging.¹⁸² A recent study by the American Academy of Dermatology estimated that 94% of women are confused by the quality and effectiveness of anti-aging treatments on the market.¹⁸³

The usual mechanism for preventing unsubstantiated drug-like product claims is to apply the intended-use analysis, which determines a product's status as a cosmetic or a drug.¹⁸⁴ The current regulation system classifies a product as a cosmetic or a drug through an analysis that places more emphasis on the manufacturer's claims and less on ingredients¹⁸⁵ or the actual physical effects.¹⁸⁶ To fall under ei-

176. Burke, *supra* note 78. Furthermore, “[i]n the last decade, the pendulum has swung and many dermatologists have embraced the cosmetics industry and formed strategic relationships It has proved to be a good partnership all around, as consumers demand more science in their skin care.” *Id.*

177. See Lewis, *supra* note 69. In a survey, “many said they expect a product to prevent or slow the formation of wrinkles if it makes such a claim on its packaging.” *Id.*

178. See *id.* (discussing a 1994 FDA survey about consumer perceptions about cosmetic labeling claims).

179. See Liang & Hartman, *supra* note 30, at 263.

180. Laurel Brown, COSMECEUTICALS OR COSMEPSEUDOCALS: EXAMINING THE FDA'S UNDER-SIGHT OF CELEBRITY DERMATOLOGISTS IN THE COSMECEUTICALS INDUSTRY (May 2005) (unpublished paper, Harvard Law School), <http://leda.law.harvard.edu/leda/data/722/brown05.pdf>.

181. See Lewis, *supra* note 69.

182. See *id.*

183. See Geria, *supra* note 17, at 41.

184. Heymann, *supra* note 36, at 365.

185. See Sarah E. Schaffer, *Reading Our Lips*, 62 FOOD & DRUG L.J. 165, 213–15 (2007).

ther the “cosmetic” or “drug” regulatory schemes, the product must be “intended” for use as a “cosmetic” or a “drug,” respectively.¹⁸⁷ The intended use is determined by the objective intent of the manufacturer, as shown by “labeling claims, advertising matter, or oral or written statements,” as well as evidence of the labeler’s knowledge of the product being offered or used for a particular purpose.¹⁸⁸ However, intended use may be difficult to police because the “status of a product may change according to the whims of the manufacturer, depending on the advertising claims the manufacturer has promulgated, the label, promotional materials, and ‘any other relevant source.’”¹⁸⁹ A manufacturer can avoid extensive regulation and premarket testing, regardless of the product’s safety, merely by drafting advertising claims in vague, unverifiable language.¹⁹⁰

The intended-use analysis discourages cosmetic companies from making unsubstantiated drug-like product claims for anti-aging skin-care cosmetics because drug-like product claims will result in the application of drug regulation requirements.¹⁹¹ For cosmeceuticals, however, focusing on the intended use could lead to classification of one product as a cosmetic while another with the same ingredients is classified as a drug, which may be confusing for consumers. For example, tretinoin (retinoic acid) is an ingredient classified by the FDA as a drug for treating acne and certain other skin conditions because it increases collagen by affecting the skin at a cellular level.¹⁹² Yet tretinoin may also be found in cosmetics.¹⁹³ Some cosmetic manufacturers also play with ingredient concentrations to avoid falling into the drug category.¹⁹⁴ Certain ingredients may have only drug functions and no cosmetic functions, or cosmetic effects at low concentrations and drug effects at high concentrations.¹⁹⁵ If the concentration of some key ingredients is too low, the consumer may be essentially paying an exor-

186. Liang & Hartman, *supra* note 30, at 252–53 (labeling and promotional claims can bring a product under the definition of a drug, regardless of the actual physical effects).

187. Heymann, *supra* note 36, at 365.

188. Greff, *supra* note 55, at 254 (citing 21 C.F.R. § 210.128 (2008)).

189. Heymann, *supra* note 36, at 365–66.

190. *Id.*

191. *See* Greff, *supra* note 55, at 250.

192. *See Creams & Cosmetics*, *supra* note 9, at 1.

193. *Id.*

194. Liang & Hartman, *supra* note 30, at 266.

195. *See* Greff, *supra* note 55, at 255.

bitant price for simple moisturizer.¹⁹⁶ Consumer confusion also occurs from closely related but different compounds, such as those derived from the same vitamin.¹⁹⁷

Drug-like names for new cosmeceuticals are also confusing to consumers.¹⁹⁸ These days, the “cosmetics counter is looking more and more like a chemistry lab.”¹⁹⁹ Kiehl’s skincare collection carries labels such as “lycopene facial moisturizing cream” and “anti-oxidant skin preserver,”²⁰⁰ Olay has “derma-3X,” L’Oréal has “boxwelox,” and Revlon has “pro-hydroxy and phyto-matrix.”²⁰¹ Estée Lauder’s Perfectionist [CP+] uses “triple enzyme technology” with “patent-pending triple enzyme technology and [Estée Lauder] exclusive Poly-Collagen Peptides.”²⁰² Some antiwrinkle cosmetics use medical terms, such as “serum,” without specific definition.²⁰³ “Serum” is otherwise known as a part of blood in “blood serum.”²⁰⁴

IV. Recommendation

Various proposals have been made on how to deal with cosmeceuticals, including adjusting the existing cosmetic and drug regulatory categories, adding a third category, or requiring premarket testing.²⁰⁵ However, many of these proposals have serious flaws. First, modifying existing categories would inevitably result in the same difficult line-drawing problem as under the current system. If the drug category was expanded to include more cosmeceuticals, the emphasis on strict requirements for stronger drugs would be reduced. Drug requirements should not be reduced because it is better to err on the side of caution in protecting consumers from likely risks. Increasing regulations on all cosmetics would be the more reasonable choice in

196. See Liang & Hartman, *supra* note 30, at 266.

197. Tex. Coop. Extension, Tex. A&M Univ. Sys., *Regulated? Effective? Or Not?*, in HEALTH HINTS, *supra* note 9, at 4, 4. For example, both retinol and retinoic acid are derived from vitamin A. *Id.*

198. See Barbara Righton, *Rip Van Wrinkle to the Rescue*, BAZAAR, Jan. 23, 2006, at 54.

199. *Id.*

200. Dubecki, *supra* note 34, at 3.

201. *See id.*

202. *See* Estée Lauder, *supra* note 13.

203. *See* Navin M. Geria, *Take a Closer Look at Anti-Aging Serums*, HAPPI, June 1, 2006, <http://www/happi.com/articles/2006/06/antiaging-cosmeceutical-corner> (describing serum use and some antiwrinkle serums with their effects).

204. *See id.*

205. *See* Liang & Hartman, *supra* note 30, at 279–80.

light of safety concerns, but feasibility becomes a problem. The cost of government regulation over all cosmetics might not be justified when the combined overall risk is minimal. Additionally, overly burdening cosmetics companies by simply adding drug-level requirements across the board could reduce availability of beneficial cosmetic products at low prices due to manufacturers' costs of complying with additional regulations.²⁰⁶

Another previously suggested alternative involves modifying existing categories by adding a new third category between drugs and cosmetics.²⁰⁷ In this alternative, additional regulations would be added to address more proportionately the type of product and risk involved.²⁰⁸ Again, this method is equally troublesome because the same line-drawing difficulties that are currently present would be doubled. What is the difference between a cosmetic and a cosmeceutical, and between a cosmeceutical and a drug? While a third category might provide some more protection for consumers, each category would become harder to define. Furthermore, if the wide gray band of cosmeceuticals was a separate category by itself, the sharp distinction between a cosmetic and drug would be lost. Yet here again, it may be argued that a strong distinction is not necessary because the physical differences between a cosmetic and a drug are not so sharply distinct, but more like a gradient shift of gray.²⁰⁹ In essence, they are both substances, but one has a more potent effect on the body and is marketed as such.²¹⁰

A long-term solution, more effective than the present-day temporary fixes that focus on specific cosmeceuticals, is to use remedies that treat the problems directly. There are two main components to this proposed solution: a notice system regarding risk and consumer education about the cosmetic-drug distinction. Additionally, overall stricter policing of product claims is desired.

206. Greff, *supra* note 55, at 250.

207. Heymann, *supra* note 36, at 373.

208. *Id.*

209. *Id.*

210. *See id.* at 372.

A. The Notice System

Many consumers have the perception that products for sale on the mass market are thoroughly tested and safe.²¹¹ They assume that products carrying a higher health risk require a prescription or would be available only through specialists.²¹² These assumptions are incorrect because products are regulated as drugs based primarily on the manufacturer's claims about the intended use of the product and less on the actual ingredients used.²¹³

Consumers can be broken down into different types: those who want anti-aging skincare products and others who are merely looking for a general cosmetic and are drawn by the anti-aging claims to purchase the skincare product with the alleged anti-aging characteristics.²¹⁴ A labeling notice system would target the unknown-health-risk problem by allocating the risk to those consumers who want the latest anti-aging product, despite its relatively untested status. These consumers would then also be aware of the potential for undesired side effects. Consumers who merely wanted traditional moisturizers and cosmetics would avoid these items or would at least be on notice of possible risks. The strength in using a notice system is that it would be adaptable to future cosmeceuticals, including those employing new technology, such as nanotechnology, which may not change the ingredient list.²¹⁵

Possible notice systems could include a label mark and a rating system. For example, a three-color code using red, yellow, and green would indicate corresponding levels of risk or the relatively untested status of a product. Red could identify new products in comparison with stable products that have been available on the market for forty or fifty years. Another possible notice system is a label mark presenting a number that represents the years the product has been available. This method would require a determination of which point in time the

211. See Lewis, *supra* note 69. "Consumers believe that 'if it's on the market, it can't hurt me.'" *Id.* (quoting John Bailey, acting director of the FDA Office of Cosmetics and Colors).

212. See *id.*

213. See CFSAN, COSMETIC, DRUG, OR BOTH?, *supra* note 37.

214. See Rogers, *supra* note 144. A skincare consultant stated, "We are seeing a generation of baby boomers who don't want to grow old or look old and, if things work, they are prepared to spend the money to pay for them." *Id.*

215. Andrew Bridges, *FDA: No Need to Flag All Nanotechnology*, USA TODAY, July 25, 2007, http://www.usatoday.com/tech/news/nano/2007-07-25-fda-nanotechnology_N.htm.

years should be counted from, such as the time the particular ingredient became available in products sold anywhere, the time the product became available, and the like. A taskforce would need to examine other notice systems to determine which system would fit best in this case.²¹⁶ A notice system could also be a warning or disclaimer, similar to the statement used for vitamin supplements: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any diseases."²¹⁷ The notice system could also be simply a symbol on certain products, functioning similarly to a biohazard symbol. Placing the notice near the ingredient list would also conveniently allow consumers to become familiar with substances used in the products.²¹⁸

Ideally, the notice system should be facially neutral to avoid creating immediate alarm or excessive negative associations with new products. The purpose would simply be to inform consumers of higher risk, but not to insinuate the product is actually unsafe. Likewise, the notice system should not give consumers a false security that other cosmetic products are completely safe if they do not have the mark of a new product. Using systems that might imply one type of cosmetic is better than another, such as a star rating, should be avoided.

Some difficulties with choosing any rating system include determining when to shift products from one category to the next. Another challenge to the notice system is its implementation. The FDA would be burdened with the task of determining the best way to educate the public about the notice system. This could be done through signs in sales locations or information provided from the manufacturers with the products. Also, a difficult problem with any notice system is enforcement of the system itself. To realistically minimize its cost, a labeling notice system would be most practical as a voluntary

216. Other rating systems include the home-energy rating, which measures energy efficiency of homes, appliances, and the like. RESNET, Frequently Asked Questions, http://www.resnet.us/ratings/overview/faq_rating.htm (last visited Oct. 17, 2008). This system uses yellow energy guide stickers to notify consumers. Energy Star, Learn More About EnergyGuide, http://www.energystar.gov/index.cfm?c=appliances.pr_energy_guide (last visited Oct. 17, 2008).

217. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FOOD & DRUG ADMIN., OVERVIEW OF DIETARY SUPPLEMENTS (2001), <http://www.cfsan.fda.gov/~dms/qa-sup12.html>.

218. Lewis, *supra* note 69. The ingredient list is the best place for a consumer to readily find out what they are buying. *See id.*

program for manufacturers, as opposed to a mandatory program. Furthermore, there would need to be sufficient incentive for manufacturers to participate. Perhaps by alerting consumers to this system, a demand could be created for products that participate in the notice system. As long as the system operated in a neutral way, it would not necessarily dissuade consumers from purchasing products with cutting-edge ingredients and technology. Consumers who want the latest anti-aging product would still create a demand for new products despite higher risks.

B. Consumer Education

While outlandish claims have always been a part of the beauty industry,²¹⁹ surveys show that consumers generally believe cosmetic product claims.²²⁰ Some educated cosmetics consumers may be aware that there are no government standards on marketing phrases like “dermatologist-tested,” “allergy-tested,” “natural,” and “hypoallergenic,” and that these are phrases employed for marketing purposes only, but many consumers do not understand this.²²¹ Manufacturers may describe AHAs as “natural products derived from fruit,” but being “natural” does not necessarily make a product safer.²²² Even less likely is a cosmetics consumer who understands the cosmetics with the chemical, drug-like names and terms describing nanotechnology. Ingredient lists may be the only current source of reliable government-required information,²²³ but with the advent of technologies like nanotechnology, where the risk changes depending on the size and not the particular ingredient, this list is no longer as reliable an indicator.²²⁴

Even if ingredients are not physically harmful, “at often exorbitant prices they could remove more cash from your wallet than wrinkles from your skin.”²²⁵ Anti-aging skincare products target aging

219. Branna, *supra* note 6.

220. See Lewis, *supra* note 69.

221. See *id.*

222. See Brody, *supra* note 135.

223. See Lewis, *supra* note 69.

224. See Philip Ross, *Tiny Toxins?*, TECH. REV., May 2006, <http://www.technologyreview.com/nanotech/16814/pagel>.

225. *Skin Care and Repair*, *supra* note 24.

adults,²²⁶ including men,²²⁷ and this is the group who will ultimately pay the price for misleading claims.²²⁸

Information is already available to the consumer through some sources. Specific cosmetic ingredients can be referenced through the International Cosmetic Ingredient Dictionary and Handbook, published by the CTFA.²²⁹ Articles available in popular magazines discuss cosmetics as well.²³⁰ It may not be realistic to expect to educate the majority of cosmetics consumers about the details of the many new cosmeceutical products, but consumer confusion can be minimized by re-educating consumers about the basic difference between cosmetic and drug classifications.

Consumers today are misled into believing many anti-aging skincare cosmeceutical products are like drugs.²³¹ In order to effectively protect consumers from false expectations, the presence of a bright-line difference between the categories should be reaffirmed and kept sharp and distinct: products that are drugs must undergo significant testing and products that are cosmetics are virtually unregulated.²³² Consumers should not believe cosmetic products will function like drugs. Cosmetics, regardless of their product claims, are generally limited to products that merely provide temporary improvement of appearance and feel, whereas drugs may have an actual physiological effect.²³³ The FDA has consumer education information available,²³⁴ but it is not distributed widely enough to reach a large percentage of cosmetics consumers.²³⁵ If consumers understand the categories, then cosmetic claims will not be as misleading.

226. Ava Caridad, *Forever Young*, HAPPI, May 1, 2007, <http://www.happi.com/articles/2006/05/forever-young>.

227. See, e.g., Burke, *supra* note 78.

228. See *Skin Care and Repair*, *supra* note 24.

229. Lewis, *supra* note 69. The Handbook is available at most public libraries or at the Office of Federal Register, 1100 L St., N.W., Washington, DC 20408. *Id.* The FDA recognizes this association as a reliable source for which substances have been identified as cosmetic ingredients, as well as their definitions and trade names. *Id.*

230. See, e.g., Newman, *supra* note 28, at 193.

231. See Geria, *supra* note 17, at 38.

232. See Heymann, *supra* note 36, at 363.

233. Liang & Hartman, *supra* note 30, at 261.

234. See, e.g., Lewis, *supra* note 69; U.S. Food & Drug Admin., How Smart Are You About Cosmetics?, Dec. 2000, <http://www.cfsan.fda.gov/~dms/costf-1.html> (online quiz testing FDA regulations).

235. See U.S. Food & Drug Admin., Consumer Health Information, <http://www.fda.gov/consumer>. FDA consumer information is available online or by request. See *id.*

V. Conclusion

Millions of aging consumers use anti-aging skincare cosmetic products as part of their daily routines without considering the possibility of health risk, trusting that the products will do what the manufacturers have claimed.²³⁶ With the introduction of more and more anti-aging skincare cosmeceuticals into the mass market, the FDA must be prepared to handle new products that do not comfortably fit within current cosmetic and drug categories. A poor response to these new products would be to wait and react to adverse results as they appear.

Anti-aging skincare cosmeceuticals are on the market *now*. The main problems associated with these products are unknown health risks and consumer confusion about the status of a product as a cosmetic or drug. The fix does not have to be as extensive as modifying FDA regulations of cosmetic and drug categories. Rather, a combination of solutions, including a notice system and consumer education, as well as stricter policing of product claims, may drastically reduce the problems.

236. Rogers, *supra* note 144.