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COSMECEUTICALS: A REVOLUTION IN COSMETIC MARKET

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Abstract

The term cosmeceutical was coined by Raymond Reed but the concepts were further popularized by Dr. Albert Kligman in the late 1970's. Cosmeceuticals are used for nourishing as well as improving the appearance of the skin, and are also documented as effective agents for treating various dermatologic conditions. Cosmeceutical preparations from herbal origin are most popular among consumers, as these agents are mostly non-toxic and possess strong antioxidant activity. The use of the cosmeceuticals has drastically risen in recent years. The cosmetic definition, labeling, safety and stability studies and the legal authority have their own impact on manufacture and sale of cosmetic products. The review is done through the various published researches in this field across the world. The research paper also gives a brief idea of different rules and regulation that govern the cosmetic industry in major markets of the world. This paper is to expand the recent knowledge about Cosmeceuticals.

Keywords: Cosmeceuticals, Hydroxy acids, Retinoids, Antioxidants.

Introduction

Cosmeceuticals are created by pharmaceutical companies and the derma genetics line of “genetically customized” skin care product is an example. Gene link, Inc, is a genetic biosciences company with a focus on biomedical projects. The pharmaceutical companies and hospitals are among the primary customers of Gene link. However, as this specific line of “genetically customized” skin care products are solely being marketed as just that, skin care products, this product will likely be classified as cosmetics.

The word “cosmetic” is derived from the Greek word “Kosmos” meaning “to arrange”. In the late 10,000 BC, cosmetics were very important in Egyptian health and Hygiene (**Journal Week.com 2011:26 September 2011:11:00 pm**). Tracing the origin of cosmetics, the first recorded use of cosmetic is attributed to Egyptians, circa 4000 BC (**Narada, 2010**). The ancient Sumerians and Hebrews also applied cosmetics. In other cases, such as European cosmetic known as Cerus was used from the second century to the 19th century (**Kaushik, 2005**). Cosmetics are products that are used to clean and beautify the skin (**Millikan, 2001**). The first recorded use of cosmetics is attributed to Egyptians in 4000 B.C (**Rona et al, 2004**).

Cosmetic history includes facts about how Egyptian society used makeup products. For the Egyptian, cosmetics were used particularly for their spiritual values, as they were religious group. The dark colour around the eyes was intended imparts toward the evil eye and please the god. Cosmetic history tells us that chemicals used for early cosmetics were often dangerous, such as those used for making Mesdemet and kohl.

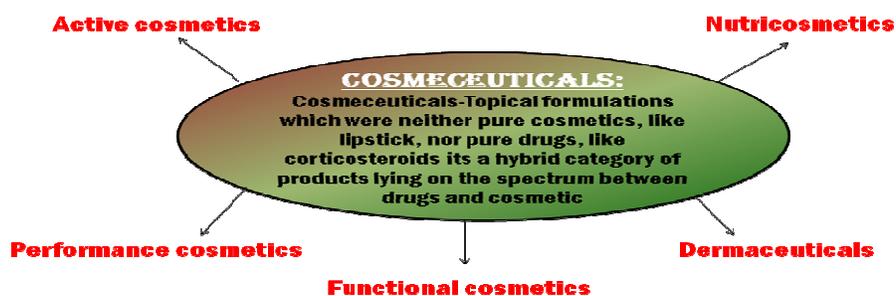
During the Edwardian society days, around 1900, middle aged women did a lot of entertaining and as hostesses, they had to look their best, which to them, meant looking as younger as possible (**Martell, 2011**). These society women needed all the help they could get to offset the effect of their high life styles. Edwardian women relied on cosmetics, especially face creams and anti-aging products (**Martell, 2011**). As the popularity of the beauty salons increased, in the beginning of the 20th century, there was no turning back for the cosmetic industry. Sale of cosmetic started with Selfridge (a Saloon) in 1909. Anti aging and skin nourishing products totalled nearly \$ 17.7 billion in worldwide retail sales in 2008, **according to Euromonitor**. The firm projects that this segment will go to \$ 22.1 billion in worldwide retail sale in 2013. US based cosmetic firm Avon products leads the antiaging/skin nourishing segment with approximately \$ 1.16 billion in 2008 worldwide retail sales, followed by UD peer Proctor & Gamble, with \$ 1.1 billion for its Olay product line.

Cosmeceuticals with different names

The term cosmeceuticals is used with different names. For all the terms the definition remains the same i.e. cosmeceuticals are the formulations which were neither pure cosmetics, like lipsticks, nor pure drug, like corticosteroids. It is a hybrid category of products lying on the spectrum between drugs and cosmetics. The

various terms by which cosmeceuticals are substituted are: (Kamal, 2007).

According to Jimtaisong (2009), the alternative terms for cosmeceuticals are:



The cosmetic industry registered impressive sales worth Rupees 422.3 billion (US \$ 9.3 billion) in 2010. The sector has mainly been driven by improving purchasing power and rising fashion consciousness of the Indian population. Moreover, the industry players are readily spending on the promotional activities to increase counter awareness. The growth of this cosmeceutical market is around 10 to 15 percent each year, reports Health World Online. The cosmeceuticals market, particularly skin care, continues to grow at about double the pace of the cosmetic and toiletries market. The cosmeceutical products are classified into three major categories.

The term cosmeceuticals is used by many skin care companies, especially those sold or endorsed by dermatologists to give the impression the products have more effective and more biologically active ingredients than just ordinary cosmetics. Cosmeceuticals are nothing more than a marketing term with illusion of grandeurs. The concept of cosmeceuticals is spreading its wings rapidly all over the world and cosmetics are no longer only restricted to beauty and skin care products. Pharmaceuticals are making rooms into the cosmetic world at a great pace and resulting in the genesis of “cosmeceuticals” which are not only contains the cosmetic ingredients but also contains certain pharmaceutically active ingredients.

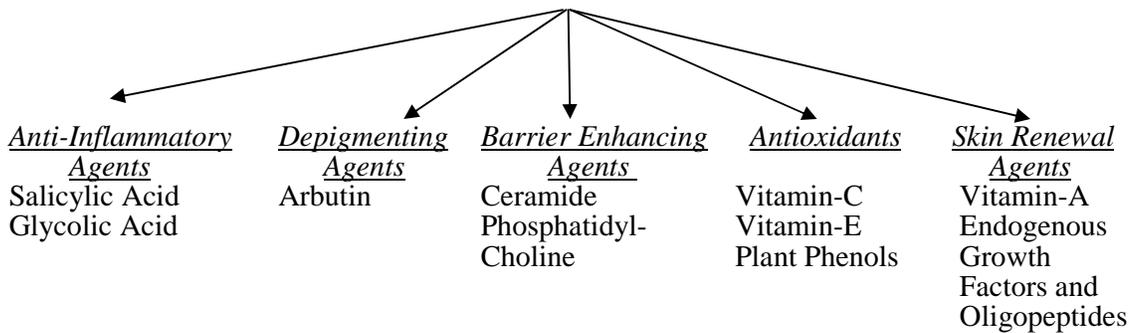
Ingredients used in Cosmeceuticals

The ingredients that are used in cosmeceutical products can be divided into five categories:

Ingredients play as one of the important role in safety using the cosmetic product. As mentioned by (EWG, 2007) through a new investigation of 833 name-brand sunscreens, they found widespread evidence that many products on the market are not safe and effective, including one of every eight high-SPF sunscreens that does not protect from UVA radiation. They have also identified 135 products that offer very good sun protection with ingredients

that present minimal health risks to users.

COSMECEUTICAL INGREDIENTS



Cosmetics Vs Drug:

There are multiple slightly variable definitions of both ‘drugs’ and ‘cosmetics’, but some commonalities do exist.

The term cosmetic refers to a preparation designed to enhance the body superficially to hide a real comprehended deficiency or flaw, by direct application. This application is considered to be decorative, lacking in depth or significance, as opposed to a response to a medical requirement. The definition of a drug is more complex.

Generally, a drug is a chemical substance which, when absorbed into a living organism, alters normal function. Organism, tissue or cell by their introduction into body from outside the organism.

The pharmacology definition of a drug will apply -" a chemical substance used in the treatment, cure, prevention or diagnosis of disease or used to otherwise enhance physical or mental well-being, for a limited duration or indefinite period of time."

Individual governments regulate the availability of drugs to the public.

- 1: Over-the-counter (OTC) medication is available from pharmacies.
- 2: Behind-the-counter medication (BTC) medication must be dispensed by pharmacist, but does not require the authority of a doctor, and finally
- 3: Prescription-only medicine (POM) can only be prescribed by a licensed medical professional.

There are also numerous bodies that regulate drugs in the market place:

- 1: The Medicines and Healthcare products Regulatory Agency (MHRA)- is a government agency responsible for ensuring that medicines and medical devices work and are acceptably safe. They are responsible for public information as well the investigation and handling of complaints and patient feedback.

2: The National Biological Standards Board (NBSB)- is a non-departmental public body, established in 1975 by Act of Parliament. The board takes responsibility for safe-guarding and advancing public health by assuring the

Cosmetics Vs Cosmeceuticals:

Cosmetics

- **FD&C Act** defines a cosmetic by its intended use meaning, cleansing, beautifying, promote attractiveness or altering appearance.
- Cosmetic products only deliver their ingredient at a very superficial level into the skin **(Anthony, 2009)**.
- Cosmetics do not delay your skin's aging process because they work at the uppermost layer of the epidermis which is topmost layer of the skin **(Anthony, 2009)**.

Cosmeceuticals

- Cosmeceutical products have pharmaceutical benefits to the skin **(Invigor8.com)**.
- Cosmeceutical products contain active ingredients that act on the skin cellular structure through topical application **(O'Lenick, 2009)**.
- Cosmeceuticals are more concentrated, pure and more effective **(O'Lenick, 2009)**.

Cosmeceutical Market

Pharma and cosmetics market in India is valued at about Rs.35000 crores, and growing at 10 % per year. Carving out a niche of Rs. 50 crores in this market is fairly easy if the products chosen can catch the fancy of the consumer.

The global cosmetic and toiletries industry saw another year of strong growth in 2007 to reach a value of 290.9 billion. **According to Euromonitor International Research** the market grew by 6 percent which represents only a slight slowdown of the 2006 figures (274.7 billion). The global ranking of major cosmetic and toiletries manufacturers have not changes since 2006. Procter & Gamble, L'Oreal and Unilever occupy the top three places globally, accounting for 30 percent of the market. Unilever demonstrated the strongest growth, 7.7 percent in 2007, while Procter & Gamble and L'Oreal increased their sales by roughly 5.5 percent each.

According to a recent AC Nelson study, the fast moving consumer goods market has shown a steady growth of nearly 20 percent during the last two quarters of 2008. Interestingly, the skin care product growth rate has jumped from just 5 percent to 30 percent in the same time period, this is due, in part, to activities in rural market where there is an increased awareness and an underlining demand for beauty products. **In a recent report by AC Nelson**, the skin whitening market currently is the fastest growing market segment, at an annual growth rate of 85 percent. With an expected growth of 11 percent in 2009, the personal care segment broke an 18 year old record in the top of mind survey conducted by **Datafolha institute (Brazil)**. Despite market slow down, India remains one of the

fastest growing markets globally, growing at 13 percent per annum and valued at \$ 6.3 billion. As the middle class consumer base and its disposable income grows, the market is moving nearly four times faster than the \$ 52 billion valued of mature beauty market, **according to a recent report by market research firm Kline & Co.**

In 2009 the top five countries of origin for import of cosmetics and skin care products into Hong Kong were France (25 percent), Japan (17 percent), China (15 percent, United States of America (15 percent) and the United Kingdom (35 percent). The total import of cosmetic and skin care products dropped slightly in 2009 after a decade of steady increase. The expected market growth for 2007 to 2012 is established to be 6 percent. Western Europe and Australia which spend a combine \$ 7.7 billion on wrinkle reducing facial creams in 2007, **according to Euromonitor Internationals** new 2008 cosmetic and toiletries database. Despite challenging economic conditions, the company reportedly generate double digit growth in revenues on a local currency basis in Japan, their largest market. Cosmeceutical is the fastest growing segment of the natural personal care industry with worldwide annual sales over \$ 14 billion. The category is projected to grow 8 percent to 12 percent annually, **according to High Bean Research.**

Some of the other medication applications of the cosmeceutical products are:

- Anti-fungal & Anti-Bacterial
- Skin-Whitening Agent
- Anti-acne Agents
- Soothing, Smoothing, Moisturizing or Protective Agents (such as calamine)
- Under eye dark circle
- Anti-Ageing & Anti-Wrinkle

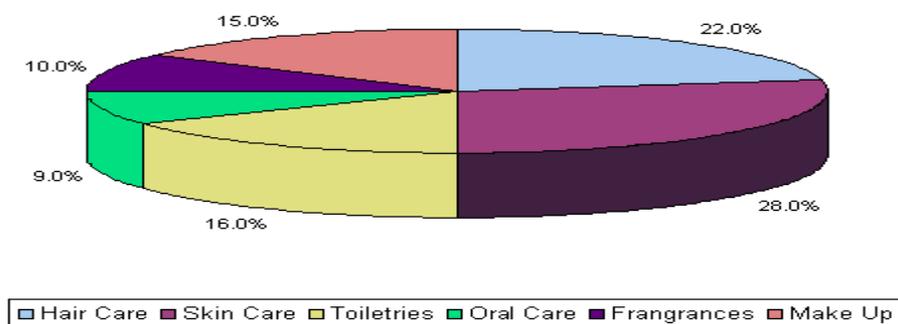
Total cosmeceuticals sales by country (US\$M), 2001-2011.

US\$	2001	2006	2011	CAGR 01-06	CAGR 06-11
France	672	904	1,161	6.1%	5.1%
Germany	538	698	865	5.4%	4.4%
Italy	497	655	805	5.7%	4.2%
Netherlands	106	131	157	4.3%	3.7%
Spain	234	329	423	7.0%	5.2%
Sweden	111	127	144	2.7%	2.6%
UK	421	526	637	4.6%	3.9%
Rest of Europe	511	671	839	5.6%	4.6%
Europe Total	3,090	4,041	5,031	5.5%	4.5%
US	3,003	4,150	5,386	6.7%	5.4%
Europe and United States	6,093	8,191	10,417	6.1%	4.9%

Source: Data monitor analysis

Innovations in cosmeceutical products over the next few years will come primarily in the following areas:

- Proof of efficacy of ingredients, particularly natural extracts, will become more important because consumers have a wide variety of choices and will discontinue use of ineffective products
- Natural products and extracts will continue to replace chemical materials, and plants and fermentation will increasingly replace animals as ingredient sources
- Delivery systems will be more complex and effective, offering triggered and controlled release of actives, and the research and development of nanostructure delivery systems will continue
- Sunscreen actives will be increasingly present in daily wear products and new actives will offer broad-spectrum UV coverage and/or higher sun protection factors
- Regulation of cosmetic and drug products will be harmonized globally, particularly between North America, the European Union, and Japan Technology Catalysts' Consumer Care research and business strategy staff has completed an extensive analysis of the technologies representing the next-generation ingredients, formulations, and delivery systems for cosmeceuticals. They have identified business opportunities in the cosmeceutical segment of the cosmetic and toiletries industry via personal interviews with inventors, companies, and organizations around the world.



Source: www.ijptonline.com

Some Common Types of Cosmeceuticals:

- 1) Hydroxy acids.
- 2) Botanicals.
- 3) Depigmenting agents.

- 4) Exfoliants.
- 5) Moisturizers.
- 6) Topical peptides.
- 7) Retinoids.
- 8) Sunscreens.
- 9) Antioxidant.

1. Hydroxy Acid

Also referred to as fruit acids, they are a common ingredient found in cosmeceutical products. Examples include: citric acid, malic acid, lactic acid.

AHAs improve skin texture and reduce the signs of aging by promoting cell shedding in the outer layers of the epidermis and by restoring hydration. One hypothesis suggests that AHAs reduce the calcium ion concentration in the epidermis and, through chelation, remove the ions from the cell adhesions, which are thereby disrupted, resulting in desquamation. This is enhanced by cleavage of the endogenous stratum corneum chymotryptic enzyme on the catherins, which are otherwise protected from proteolysis by conjugation with calcium ions. The resulting reduction of the calcium ion levels tends to promote cell growth and slow cell differentiation, thus giving rise to younger looking.

Alpha Hydroxy Acids (AHAs)

α -Hydroxy acids, or **alpha hydroxy acids (AHAs)**, are a class of chemical compounds that consist of a carboxylic acid substituted with a hydroxyl group on the adjacent carbon. They may be either naturally occurring or synthetic. AHAs are well-known for their use in the cosmetics industry. They are often found in products claiming to reduce wrinkles or the signs of aging, and improve the overall look and feel of the skin. They are also used as chemical peels available in a dermatologist's office, beauty and health spas and home kits, which usually contain a lower concentration..Although their effectiveness is documented numerous cosmetic products have appeared on the market with unfounded claims of performance. Many well-known α -hydroxy acids are useful building blocks in organic synthesis: the most common and simple are glycolic acid, lactic acid, citric acid, mandelic acid.

AHAs are a group of organic carboxylic compounds. AHAs most commonly used in cosmetic applications are

typically derived from food products including:

- a) Glycolic acid (from sugar cane),
- b) Lactic acid (from sour milk),
- c) Malic acid (from apples),
- d) Citric acid (from citrus fruits),
- e) Tartaric acid (from grape wine).

For any topical compound, including AHA, it must penetrate into the skin where it can act on living cells. Bioavailability (influenced primarily by small molecular size) is one characteristic that is important in determining compound's ability to penetrate the top layer of the skin. Glycolic acid having the smallest molecular size is the AHA with greatest bioavailability and penetrates the skin most easily; this largely accounts for the popularity of this product in cosmetic applications.

Beta Hydroxy Acid

Beta hydroxy acid is not a single substance; instead, it is a term used to describe a family of organic acids. These organic compounds may either be naturally occurring or synthetic. In their natural chemical state, beta hydroxy acids are found in the body, in fruits, and in the bark of the willow tree. Synthetic versions have proven to be as effective as the natural forms and are used in an array of medicines and commercial products. The beta hydroxy acid family consists of salicylic acid, carnitine, betahydroxybutyric acid, 3-hydroxypropionic acid, and beta-hydroxy beta-methylbutyrate acid. Salicylic acid is the most well-known beta hydroxy acid and the only one used in dermatology. Derived from aspirin, it is widely used in both cosmetics and skin care products. For decades, salicylic acid has functioned as the main ingredient in acne treatment medicines. Since beta hydroxy acids are oil soluble, they are able to penetrate beneath the skin into the pores. Due to this, beta hydroxy acid is an effective ingredient in modern antiaging products and skin cleansers.

Carnitine is biosynthesized from amino acids in the body. It is used during the metabolic process that breaks down fats. Outside of the body, carnitine is found in high concentrations in dairy products and red meat. As a supplement, this beta hydroxy acid is mainly used to treat heart-related conditions and symptoms of kidney

disease. Carnitine is also marketed as a weight-loss supplement, although its effectiveness in helping dieters has yet to be determined.

Beta-hydroxybutyric acid is used as a source of energy by the brain when blood glucose levels are low. Industries use the synthetically developed form of this acid, which is produced by bacteria, as part of the manufacturing process in making biodegradable plastics. Another beta hydroxy acid, 3-hydroxypropionic acid (3-HP), is also produced in the body, but has been synthesized in laboratories by using microbes. It is an important component in the industrial production of specialty chemicals such as polyesters.

2. Botanicals

Botanicals comprise the largest category of cosmeceutical additives found into the marketplace today. Some botanicals that may benefit the skin include: green tea extract, ferulic acid, and grape seed extract.

Ferulic acid: This compound, which is derived from plants, is considered to be a potent antioxidant, and has been shown to provide photoprotection to skin. Furthermore, when ferulic acid is combined with vitamins C and E, the product has been shown to provide substantial UV protection for human skin. Moreover, Murray et al. report that because its mechanism of action is different from sunscreens, ferulic acid could be expected to supplement the sun protection provided by sunscreens.

Grape Seed Extract: This botanical has been established as a potent antioxidant and has been shown to speed wound contraction and closure. Topical application of grape seed extract has also been shown to enhance the sun protection factor in humans.

3. Depigmenting Agent: Skin-lightening agents added to product formulations have become increasingly popular. Common depigmenting ingredients include hydroquinone, ascorbic acid (vitamin C), kojic acid, and licorice extract (glabridin).

Hydroquinone: Hydroquinone has been the agent of choice for skin lightening. The US FDA has proposed concentrations between 1.5% and 2% in skin lighteners. A recent report suggested that this concern has been based mainly on studies with animal models utilizing long-term exposure at high dosages are carcinogenic. Routine topical application may pose no greater risk than that from levels present in common foods.

Ascorbic Acid (Vitamin C): Ascorbic acid is a naturally occurring antioxidant found in citrus fruits and leafy green vegetables. It is hydrophilic, so skin penetration is low.

Kojic Acid: Kojic acid is a less commonly used bleaching agent. When combined with dipalmitate, there is improved skin penetration and greater stability, but there is little research to support its efficacy.

Licorice Extract (Glabridin): Several studies on melasma have shown good efficacy with only mild irritation that disappeared with discontinuation.

4. Exfoliants:

Exfoliants promote skin turnover by removing adherent cells in the stratum corneum. Common exfoliants found in cosmeceutical preparations include salicylic acid (SA), lactic acid, and glycolic acid. There are concerns that repeated use of SA and AHAs could cause the dermis and epidermis to be more vulnerable to penetration by UV radiation. Therefore, patients should be advised to use adequate sun protection. The Cosmetic Ingredient Review Expert Panel concluded that SAs are safe to use when formulated to avoid skin irritation and to be nonphotosensitizing, or when directions for use include the daily application of sun protection.

5. Moisturizers:

Moisturizers restore water content to the epidermis, and provide a soothing protective film. They improve the appearance and tactile properties of dry and aging skin, restore the normal barrier function of the skin, and reduce the release of inflammatory cytokines. Moisturizers comprise an important therapeutic component in the management of various skin conditions (e.g., eczema, psoriasis, pruritus, and aged skin)

6. Topical Peptides

Topical peptides are regarded as cellular messengers that are formed from amino acids and are designed to mimic peptide fragments with endogenous biologic activity. These pentapeptides (e.g., KTTKS) are comprised of a subfragment of type I collagen propeptide, and play a role in signalling fibroblasts to produce collagen in the skin, which can improve the appearance of wrinkles. One variation, the palmitoyl pentapeptide known as Pal-KKTKS (Matrixyl™, Sederma) was tested in a controlled, double-blind, left-right randomized, split-face study of 93 women between 35 and 55 years of age who had Fitzpatrick I-III type skin. Pal-KTTSK concentration was

3ppm; both groups were treated twice daily for 12 weeks. Improvements in wrinkle appearance and length were observed.

7. Retinoids

Retinoids are among the most common ingredients found in cosmeceuticals. In fact, they are the most studied and have the most data behind them. They consist of natural and synthetic derivatives of vitamin A that reduce hyperpigmentation and inhibit enzymes from breaking down collagen. Many of their cosmeceutical claims are based on data derived from studies on tretinoin and other classes of retinoid drugs. Some key retinoids include retinoic acid (tretinoin), retinol, retinaldehyde etc.

8. Sunscreen:

Sunscreens are the single most important cosmeceutical, because they protect skin against solar radiation, which is the most important damaging environmental agent. As a result, they help to prevent the signs of aging. To be effective, sunscreens should provide broad spectrum coverage that includes both UVA and UVB blocking agents to inhibit photoaging and be part of a daily skin care regimen. Sunscreens contain active ingredients that act as ultraviolet filters. The recommended application is 2mg/cm², though this is rarely achieved in real-life practice.

9. Antioxidants

Antioxidants reduce free-radical damage, thereby preventing impairment at the cellular level. They inhibit inflammation, which leads to collagen depletion, and they offer protection against photodamage and skin cancer. Common antioxidants include alpha-lipoic acid (ALA), L-ascorbic acid (vitamin C), niacinamide (vitamin B3), N-acetyl-glucosamine (NAG), α -tocopherol, and ubiquinone.

Topical Product Regulatory Issues

As mentioned previously, one significant element that has risen in prominence to help off-set the financial costs and improve profitability of a medical practice is the addition of esthetic services. One of the many challenges today is finding the balance between the fiscal bottom line and providing patients with the most cost effective care possible. This usually includes the offering of services provided by numerous light and/or laser devices with esthetic treatment regimens, fillers, and injectible neuromodulators to treat facial wrinkles. Additionally,

professional cosmeceutical products should be offered for daily use to further improve visible results and maximize benefit of in-office procedures. Optimal results are achieved with a plan between client and skin care professional, working together as a “team.” Since home care treatments make up a large percentage of a patient’s skin care program time, the skin care professional must have thorough knowledge of available options. Confidence in a well-formulated product line will then have the greatest positive impact. Because you, as the licensed skin care professional, are providing recommendations within your office, it is absolutely crucial to have a full understanding of which products are safe and effective and how to integrate them into your practice. Since clientele trust your recommendations, you must strive to become an expert regarding all aspects of skin care, including products you sell.

Estheticians and other skin care professionals are often asked these common questions from clients: What is the difference between a “professional” skin care cosmeceutical versus a brand one can find OTC at a drug or department store? Is there really a notable difference in formulations, or is it all about celebrity endorsement, fancy marketing and pretty pictures? Can one get superior results with drugstore cosmetic brands, or will results be better using professional cosmeceuticals? All too often, consumers fall under the spell of cosmetic company marketing and advertising claims, and will spend a lot of money on expensive OTC cosmetics that don’t really go beyond “feeling” or “smelling” good. The US Food and Drug Administration (FDA) recognize two distinct categories of products that affect skin conditions and diseases: pharmaceuticals and cosmetics.

Pharmaceutical ingredients are used in medicines that claim to treat specific diseases and conditions. They are available by prescription through a physician, nurse practitioner or physician assistant with a supervising doctor. Topical pharmaceuticals are drugs that penetrate through the stratum corneum barrier into the epidermis to have a measureable effect on the structure and function of the skin, and to reverse the disease state. FDA approval requires proof of effectiveness by double-blind randomized prospective controlled clinical trials in hundreds of people. The study should be conducted by an independent research group to prevent bias, even though it is paid for by the company sponsoring the drug. Product development costs usually exceed \$230 million and take seven to 12 years for approval of a single prescription drug by this New Drug Application (NDA). Safety and stability

studies of the products must be completed prior to the final (phase III) clinical trials.

A group of nonprescription ingredients in FDA over-the-counter (OTC) drug monographs stipulate that the use of ingredients at specific concentration ranges can be claimed to treat specific diseases, thus are OTC medicines. These include 2% salicylic acid for acne and 3% for psoriasis, 1% zinc pyrithione for dandruff shampoo, and 2% sulfur for psoriasis and acne. Companies selling these types of OTC drugs can advertise that they treat certain diseases just as prescription products can. A product must not make the treatment of a disease claim if it does not fit under an OTC monograph nor was approved by the FDA as a new drug. OTC drugs have relatively few side effects and are sold without a prescription. These types of ingredients include certain sunscreens, acne, dermatitis, dandruff and psoriasis treatments, skin protectants, topical anesthetics, and warts removers. Standardized labeling is a mandatory requirement for these types of ingredients called drug facts labels, and is usually found on the outer box or actual product packaging. This labeling clearly indicates how to use the product and what condition the product treats. Also included in the drug facts labeling are possible side effects and contraindications. Cosmetics are defined by the FDA as "...articles intended to be applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance..."¹ Skin care products that are marketed under the cosmetics category do not require a prescription and are not required to prove their marketing claims nor have any safety studies. Very low concentrations of FDA OTC monograph ingredients such as 0.4% salicylic acid fit in this category, and do not need to be listed separately on ingredient labels.

The Fair Packaging and Label Act require an ingredient listing for every cosmetic product retailed to consumers. Since cosmetic companies aren't regulated by the FDA and required to prove efficacy claims, the special active ingredient touted in the formula must only appear somewhere on the ingredient list. All the ingredients in the product are listed in order, from most weight to least weight, so if you see that "active" on the last half of the list (usually alphabetically) it is likely to be a very tiny percentage (less than 1%) of that specific ingredient. Keep in mind that formulations often do not necessarily need a high percentage of active ingredient in order to have efficacy in the skin because it is the total mix of actives plus the base that make an effective topical formulation. Moreover, many prescription ingredients are potent enough to work at 0.01% to 1.0% concentration.

Indian Regulatory Scenario

Key issues with the current Indian cosmetic regulations include the following

- Multiple and complex regulations under different bodies
- Indian cosmetic definition is narrow & restrictive
- Lack of implementation guidelines of the D & C Act for regulators for issues related to cosmetics such as
- Non uniform licensing approvals across various states
- Inconsistent approach across authorities in interpretation of a particular issue
- Absence of guidelines on product claim interpretation as well as illustrative lists of cosmetics, cause difference in interpretation between licensing authorities on product classification and hence delaying the process of product licensing and product trade cycle
- Pace of BIS Standards development/ revision are not in line with technological progress thus deterring innovation and growth.

Drugs and Cosmetics Act, 1940 governs the provisions relating to manufacture, sale, storage, distribution and import of Drugs as well as cosmetics in India. Whereas the said Act clearly defines the terms "Drug" and "Cosmetic" as under, there is no term as "Cosmeceutical" in the Act. As such nobody has a legal or statutory right to use the term for drawing benefits of any sort. For all intents and purposes either "drug" or "cosmetic" terms have to be used and usage of any other term to replace or substitute either of these two terms is simply illegal, there is no rationale. However the term "Cosmeceuticals" may be used for purposes other than legal/statutory/ drawing benefits/ seeking relaxations or concessions etc.

A comparison of cosmetic regulations between USA, EU and India

Contents	USA	EU	INDIA
Authority	<i>Fda</i>	<i>Emea</i>	<i>Cdsco</i>
Rules and regulations	<i>Food, drug and Cosmetic act</i>	<i>Council directive 76/768/eec</i>	<i>Drugs and Cosmetics act</i>
Pre-market approval	<i>Not required</i>	<i>not required by Cosmetic directive</i>	<i>Required under state government licensing</i>
Labelling	<i>Should comply with the fd&c and fp&l</i>	<i>Based on council Directive 76/768/eec</i>	<i>Should comply With part Xv of d&c Rules 1945</i>

Expiry date	No date required	Date of minimum Durability if durability is <30 months. Period After opening if Durability is >30 months	Indicated as "use before date"
Post marketing reporting System	yes. (voluntary cosmetic registration program)	N/a	N/a

Source: <http://scholarsresearchlibrary.com>

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