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Review Article

"COSMECEUTICALS": AN OPINION IN THE DIRECTION OF PHARMACEUTICALS

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ABSTRACT

Cosmeceuticals are the latest addition to the health industry and are described as cosmetic products with drug-like activities. Cosmetics are products that are used to cleanse and beautify the skin (Millikan, 2001). Pharmaceuticals are essentially drug products and are defined as products that prevent, mitigate, treat or cure disease and/or affect the structure or function of the body (Vermeer and Gilchrest, 1996). Cosmeceuticals is a deliberate portmanteau of these two terms and is intended to connote drug-like benefits from an otherwise cosmetic product. While the food, drug, and cosmetic act does not recognize the term "cosmeceutical," the cosmetic industry has begun to use this word to refer to cosmetic products that have drug-like benefits. The term cosmeceutical was coined by Kilgman, but these lines of product became popular in 1996 and have an expanding market that has rapidly reached Africa. Many scientists and health consumers in Africa may not be conversant with this line of products. They may, therefore, be under-researched or over-utilized. In the cosmetic arena, many materials are used commercially. Cosmetic ingredients previously considered "inert" have the potential to provide a biologic effect to the skin. In a cosmeceutical formulation, the boundary between an "active" and "inert" ingredient may be obscured. There is most common names of the different ingredients used in cosmeceutical products such as antioxidants, the binding agent, emollients, emulsions, humectants, lubricants, preservatives, solvents, surfactants, vehicle, etc. "Potential for cosmeceutical ingredients in the United States alone is SI00 million and includes such products as skin peelers, wrinkle creams, emollients, hair growth stimulants, skin lighteners and darkeners, and botanicals. The 75 million baby boomers are the major market for cosmeceuticals. Cosmeceuticals claims are largely unsubstantiated and the term, though misleading, has probably come to stay. The term and the target consumers appear flamboyant enough to with stand Government regulations. In a free trade world, the benefits and adverse effects of cosmeceuticals are probably optimized by frequent review to inform the clinical and public stake-holders of their uses and limitations. This comprehensive review attempts to briefly, expand the recent knowledge about cosmeceuticals.

Keywords: Cosmetics, Formulation/stability, Safety testing, Claim substantiation.

INTRODUCTION

Cosmeceuticals or cosmaceuticals are cosmetic-pharmaceutical hybrids intended to enhance the beauty through ingredients that provide additional health-related function or benefit. They are applied topically as cosmetics, but contain ingredients that influence the skin's biological function [1]. Cosmetics are products that are used to cleanse and beautify the skin [2]. The first recorded use of cosmetics is attributed to Egyptians in 4000 B.C [3]. The ancient Sumerians, Babylonians, and Hebrews also applied cosmetics. In other cases, like European cosmetic known as ceruse was used from the second century to the 19th century. The term "cosmeceutical" coined in 1961 by Reymond Reed, [4] was used to describe "active" and science-based cosmetics. The word and concept were further popularized by Dr. Albert Klingman in late 1970s. Cosmeceutical products first appeared in the world market only in 1996 [5]. The purported drugs like effects are unproven, and the term is neither recognized by the United States Food and Drug Administration (FDA) nor by any other regulatory body [6]. Between 1996 and 2007, out of over 837 articles published in reputable journals, and over 600 have used the word cosmeceuticals as an authentic term [7]. This may be the beginning of International recognition. Cosmeceutically active ingredients are constantly being developed by big and small corporations engaged in pharmaceuticals, biotechnology, natural products, and cosmetics, while advances in the field and knowledge of skin biology and pharmacology have facilitated the cosmetic industry's development of novel active compounds more rapidly [8]. Desirable features of cosmeceutical agents are efficacy, safety, formulation stability, novelty, and patent protection, metabolism within the skin and inexpensive manufacture [9]. Cosmeceutics are sold over-the-counter products and are regulated as cosmetics, not pharmaceuticals. The Government does not recognize a separate "cosmeceutical" category. This fact affects the type of product testing done, the format and substantiation of claims, and the language used in promotion of products. Lack of awareness of this important issue among physicians, skin care professionals, and consumers has led to many misunderstandings about cosmeceuticals [10]. An attempt has been made to review different types of cosmeceuticals and their regulatory aspects.

Lines of products

The lines of products of cosmeceuticals are designed both to exploit veterinary and human therapy. The main product lines of veterinary cosmeceuticals are shampoos and anti-ectoparasites. MERA-PET lines of products are probably the most popular in Europe and North America. The main product lines of human cosmeceuticals are anti-aging while very few are anti-acne or moisturizers. Common brand names include "Bliss," "MD Skin Care," "La Roche," Nu-Derm" and "SensiClear." Like veterinary cosmeceuticals, anti-aging cosmeceuticals have been formulated on sound biological grounds but with unsubstantiated clinical claims. Aging may be intrinsic or extrinsic. Anti-aging cosmeceuticals are designed to repair and/or maintain the body's maintenance and repair systems called MRSs [6]. These formed the grounds for products like cosmeceutical peptides, which may contain neurotransmitters, signal peptides or carrier proteins. Up to 500 peptides have been characterized, [11] and are theorized to increase growth factor [12]. Botanical cosmeceuticals contain botanical ingredients with traditional or folk medicine use. These often include grape seed extracts, Aloe Vera, mushrooms, olive oil, green tea, licorice, coffee Arabica and coffee berry extracts [13]. Antioxidants play a large role in the MRSs. This may explain the incorporation of vitamins C and E into cosmeceuticals sometimes called better cosmeceuticals [14]. Better cosmeceuticals may also contain niacinamide and kinetin [15].

Skin care cosmeceuticals

Cosmetics and skin care products are part of everyday grooming. Our skin, the largest organ in the body, separates and protects the internal environment from the external one. Environmental elements, air

pollution, exposure to solar radiation as well as normal aging process cause cumulative damage to building blocks of skin-DNA, collagen, and cell membranes. Therefore, protecting and preserving the skin is essential to good health. Use of cosmetics or beauty products will not cause the skin to change or heal; these products are just meant to cover and beautify. Cosmeceuticals being cosmetic products having medicinal or drug-like benefits are able to affect the biological functioning of the skin owing to type of functional ingredients they contain. There are skin-care products that go beyond coloring and adorning the skin. These products improve the functioning/texture of the skin by encouraging collagen growth by combating harmful effects of free radicals, thus maintaining keratin structure in good condition and making the skin healthier. Some of the common cosmeceutical contents are given in Table 1 [16-18].

Table 1: List of cosmeceutical ingredients with their plant sources

Ingredient	Purported action	Source
Vitamins	Antioxidant	Vitamins A, C, and E
AHAs	Exfoliates and improves circulation	Fruit acids (glycolic acid, lactic acid, citric acid, tartaric acid, pyruvic acid, maleic acid, etc.)
BHAs	Antibacterial	Salicylic acid
Essential fatty acids	Smoothens, moisturizes and protects	Linoleic and arachidonic acids
Coenzyme Q10 (Ubiquinone)	Cellular antioxidant	Naturally occurring in skin
Allantoin	Soothes	Comfrey
Aloe vera	Softens skin	Aloe vera
Arnica	Astringent and soothes	*A. montana*
Calendula	Soothes, softens and promotes skin- cell formation	*C. officinalis*
β-Bisabolol	Anti-inflammatory, antibacterial, and calms irritated skin	Chamomile flower
Cucumber	Cools, refreshes and tightens pores	Cucumber
Lupeol	Antioxidant and skin conditioning agent	*C. nurvula*
Ginkgo	Antioxidant that smoothes, rejuvenates and promotes youthful appearance	*G. biloba*
Ivy	Stimulates circulation and helps other ingredients penetrate the skin	*Hedera* spp. (ivy family)
Panthenol	Builds moisture and soothes irritation	Provitamin B5
Witch hazel	Tones	*H. virginiana*
Green tea extract	Antioxidant	Green teas
Neem oil limonoids	Antimicrobial	*A. indica*
Pycnogenol	Anti-aging effect	Grape seed extract
α-Lipoic acids, Resveratrol, polydatins	Potent free-radical scavengers and antioxidant	Fruits and vegetables
Furfuryladenine	Improves hydration and texture of the skin	Plant growth hormone
Kinetin	Free-radical scavenger and antioxidant	Plants and yeast
Sodium hyaluronate	Lubricant between skin tissues and maintains natural moisture	Natural protein
β-Carotene	Minimizes lipid peroxidation and cellular antioxidant	Carrots and tomatoes
Retinoic acid	Smoothes skin, promotes cell renewal and improves circulation to the skin	Vitamin A
Tetrahydrocurcuminoides	Antioxidant and anti-aging	*C. longa*
Centella	Skin conditioning agent, increases collagen production, improves texture and integrity of the skin, and reduces the appearance of stretch marks	*C. asciatica*
Boswellia	Anti-inflammatory and anti-aging	*B. serrate*
Coriander seed oil	Anti-inflammatory and anti-irritant, skin-lightening properties	*C. sativa*
Turmeric oil	Antibacterial and anti-inflammatory	*C. longa*
Coleus forskoflii oil	Antimicrobial, aromatherapy/perfumer	*C. forskoflii*
Arjunolic extract	Antioxidant and anti-inflammatory	*T. arjuna*
Ursolic acid	Anti-inflammatory, collagen build-up	*R. officinalis*
Oleanolic extract	Antioxidant, antifungal, improves texture and integrity of the skin	Olive leaf
Rosemary extract	Antioxidant, antimicrobial, and anti-inflammatory	*R. officinalis*
Dry extract from yarrow	Treatment of oily hair	*A. millefolium*
Licorice extract	Skin whitening properties, antioxidant, antimicrobial, and anti-inflammatory	*G. glabra*
Horse chestnut extract	Supports blood circulation, wound healing effect, and anti-inflammatory	*A. hippocastanum*
Lycopene	Smoothes skin, promotes cell renewal and improves circulation to the skin	*S. lycopersicum* (Tomato)
Epigallocatechin gallate	Antioxidant	*C. sinensis* (Green tea)
Quercetin, Epicatechin	Anti-bacterial, Astringent	*M. domestica* (Apple)
Ascorbic acid	Potent Antioxidant	*C. limon* (Lemon)
Stearic and oleic acids	Potent free-radical scavengers	*B. parkii*
2-methyl butanoic acid ester	Anti-inflammatory, antibacterial, and calms irritated skin	*A. nobilis* (Roman Camomile)
Hydroquinone mono-glucoside, myricetin, quercetin	Smoothens moisturizes and protects	*A. uva-ursi* (Bearberry)
Vitamin E	Potent Antioxidant	*H. annuus* (Sun Flower)
Vitamin B5, Potassium, polyphenols and Vitamin C	Builds moisture and soothes irritation	*P. granatum* (Pomegranate)

Contd...

Table 1: Contd...

Ingredient	Purported action	Source
Vitamin A, Sitosterol, Laserine, Epilaserine	Minimizes lipid peroxidation and cellular antioxidant	*D. carota* (Carrot)
Vitamin C, indole-3-carbinol	Antioxidant and anticancer	*B. oleracea* (Cabbage)
Curcumin, Zingiberine	Antibacterial and anti-inflammatory	*C. longa* (Turmeric)
Liriodenine, moupinamide, - Pinene	Potent antioxidant	*A. squamosal* (Sugar-apple)
Vitamin B, vitamin C, etc.	Skin conditioning agent, increases collagen production, improves texture and integrity of the skin, and reduces the appearance of stretch marks	*C. nucifera* (Coconut)
Homocysteine, allicin (diallyl thiosulfinate or diallyl disulfide)	Antioxidant and skin conditioning agent	*A. sativum* (Garlic)
Glycyrrhetinic acid, Stearyl glycyrrhetinate	Skin whitening properties, antioxidant, antimicrobial, and anti-inflammatory	*G. glabra* (Liquorice)
Constituent not reported		*M. officinalis* (Indian mulberry)
Constituent not reported		*C. aromatic* (wild turmeric)
Constituent not reported		*G. arborea* (Gambha)
Ginkgolides and Bilobalide	Antioxidant that smoothes, rejuvenates and promotes youthful appearance	*G. biloba* (Maidenhair tree)

BHAs: β-Hydroxy acids, AHAs: α-Hydroxy acids, *G. biloba: Ginkgo biloba, G. arborea: Gmelina arborea, C. aromatic: Curcuma aromatic, M. officinalis: Morinda officinalis, G. glabra: Glycyrrhiza glabra, A. sativum: Allium sativum, C. nucifera: Cocos nucifera, A. squamosal: Annona squamosal, C. longa: Curcuma longa, B. oleracea: Brassica oleracea, D. carota: Daucus carota, P. granatum: Punica granatum, H. annuus: Helianthus annuus, A. uva-ursi: Actostaphylos uva-ursi, A. nobilis: Anthemis nobilis, B. parkii: Butyrospermum parkii, C. limon: Citrus limon, M. domestica: Malus domestica, C. sinensis: Camellia sinensis, S. lycopersicum: Solanum lycopersicum, A. hippocastanum: Aesculus hippocastanum, G. glabra: Glycyrrhiza glabra, A. millefolium: Achillea millefolium, R. officinalis: Rosemarinus officinalis, T. arjuna: Terminalia arjuna, C. longa: Curcuma longa, C. forskoflii: Coleus forskoflii, C. sativa: Coriandrum sativa, B. serrate: Boswellia serrate, C. asciatica: Centella asciatica, A. indica: Azadirachta indica, H. virginiana: Hamamelis virginiana, C. nurvula: Cratacva nurvula, A. montana: Arnica montana*

Olay vitamin line, which includes vitamins A, C, D, E, selenium, and lycopene, pycnogenol plus zinc, and copper, is a well-known skin care line [19]. The treatment of aging skin with cream containing hormone like estrogen results in a fresh appearance with a rejuvenating effect [20]. Kuno and Matsumoto had patented an external agent for the skin comprising an extract prepared from olive plants as a skin-beautifying component, in particular, as an anti-aging component for the skin and/or a whitening component [21]. Dry emollient preparation containing monounsaturated jojoba esters is used for cosmeceutical purpose [22]. Martin utilized plant extract of genus chrysanthemum in a cosmetic composition for stimulating skin and/or hair pigmentation [23]. Novel cosmetic creams or gels with active ingredients and water-soluble barrier disruption agents such as vitamin A palmitate have been developed to improve the deteriorated or aged skin [24].

Sunscreens

Regular use of an effective sunscreen is the single most important step to maintain healthy, youthful-looking skin. Mainly, it is the effect of ultraviolet (UV) light from the sun that causes most of the visible effects of 'aging' skin. Traditional chemical sunscreens act primarily by binding skin protein and absorbing UVB photons (280-320 nm) and most are based on para-aminobenzoic acid (or its derivatives), cinnamates, various salicylates and benzophenones, dibenzoyl methanes, anthraline derivatives, octocrylene, and homosalate. Avobenzone (Parsol-1789) is a benzophenone with excellent UVA protection. Physical agents or sun blocks, act as barriers, which reflect or scatter radiation. Direct physical blockers include metal containing compounds such as iron, zinc, titanium, and bismuth. Zinc oxide and titanium dioxide are highly reflective white powders, but submicron zinc oxide or titanium dioxide powder particles transmit visible light while retaining their UV blocking properties, thus rendering the sun block invisible on the skin. Some commercially available sunscreens are Benzophenone-8, Neo Heliopan MA and BB, Parsol MCX and HS, Escalol 557, 587 and 597 [25]. Govier *et al*. [26] patented sunscreen composition comprising activated platelet factor as an ingredient in a cosmeceutically acceptable carrier. Such a composition in the form of a shaving cream or foam, after shave lotion, moisturizing cream, sun tan lotion, lipstick, etc. Assist in restoring the skin damaged by cuts, abrasions, sun, wind, and the like to its natural condition.

Moisturizers

Moisturizers incorporated with emollients help smoothen age lines, brighten and tone skin surface by filling space between non-living outer layer of the skin and lubricating while promoting the retention of moisture in these layers. Ingredients such as black cohosh, soy extract and vitamin A, E found in healthy remedies balancing lotion for menopausal women help diminish the appearance of fine lines and wrinkles while up-lifting the neck area and promoting moisture retention.

Bleaching agents

Bleaching agents provide sun protection that the block formation of skin pigment called melanin apart from bleaching/fading various marks such as brown marks, liver spots, melisma, etc. One of the most commonly used agent is hydroquinone, kojic acid, extract from mushroom, which may be compounded with tretinoin or topical steroids, α, β hydroxy acids, [27] is slightly less effective as an agent compared with hydroquinone. Aggressive exfoliation and sun protection are necessary for desired results. A synthetic detergent bar was developed containing hydroquinone as an agent maintaining a pH between 4 and 7 and includes a compressed mixture of a synthetic anionic detergent, hydroquinone and its stabilizer, water, a buffer which maintains the pH of the bar and excipients such as waxes, paraffin, dextrin, and starch [27]. Similarly, a skin bleaching preparation comprising hydroquinone, tertiary butyl hydroquinone, and optionally an additional stabilizer, a buffer to maintain pH between 3.5 and 7.5 [28] thus, the skin bleaching preparation is characterized by an extended shelf life due to the presence of stabilizer and the maintenance of low pH.

Hair care cosmeceuticals

Hair is a bodily feature over which humans has direct control in modifying the length, coloring and styling it according to how one wishes to appear. It plays an important role in people's physical appearance and self-perception. Among the earliest forms of hair, cosmetic procedures in ancient Egypt was hair setting using mud and hair coloring with henna. In ancient Greece and Rome, numerous ointments and tonics were used for hair beautification purpose as well as remedies for the treatment of scalp diseases. Henry de Mondeville was the first to distinguish between medicinal therapies intended to treat diseases and cosmetic agents for the purpose of beautification [29]. Today's delineation of cosmetics from pharmaceuticals has become more complex due to the development of cosmetics with physiologically active ingredients, namely the cosmeceuticals. While shampoo has been primarily used for cleaning hair and scalp, current formulations are adapted to the

variations associated with hair quality, hair care habit, and specific problems such as treatment of oily hairs, [30] dandruff, [31] and for androgenic alopecia [32] related to the superficial condition of the scalp, it is by far the most frequent form of cosmetic hair treatment.

Cosmetics for treatment of hair which is topically applied to the scalp and hair can never be used for therapeutic purposes. They must be harmless to the skin and scalp, to the hair, and to the mucous membranes and should never have any general or local toxic effects in normal conditions of their use. Mausner [33] patented a shampoo composition for cleaning hair and scalp and hair. A hair-care cosmetic compositions comprising iodopropynyl butylcarbonate and/or a solution of zinc pyrithione in N-acylethylenediamine triacetate has been patented, which includes an appropriate carrier and a non-allergenic drug extract of yarrow(*Achillea millefolium* L.), obtained by oxidation of a water-alcohol solution extract of flower tops of yarrow. The extract contains <0.5% by weight of poly-phenolic derivatives, is used for the treatment of hair, particularly oily hair, based on the extract of yarrow [30]. Genetic hair loss arising from the activation of an inherited predisposition to circulating androgenic hormones has prompted Buck [32] to patent a treatment method wherein liquid carbonic detergents are topically administered.

Conditioning agents, special care ingredients, and hair growth stimulants are part of hair cosmeceutical products. Fatty ingredients, hydrolyzed proteins, quaternized cationic derivatives, cationic polymers, and silicones [33] are some of the ingredients used to import softness and gloss found in conditioning agents. Special care ingredients are shampoos used for modifying specific problem related to the superficial scalp. They are formulated around one or more specific ingredients selected for their clinical effectiveness. All-effective antifungal agents-zinc pyrithione, octopirox, and ketoconazole [34] are some of the current anti-dandruff ingredients. Hair growth stimulants do not have any impact on hair growth due to short-contact time and water dilution. A minoxidil related compound (2,4-diaminopyrimidine 3-oxide) is a cosmetic agent with claim of acting as a topical hair growth stimulant [35] which assist in the prevention of inflammation and perifollicular fibrosis [36]. Conclusive findings to a certain extent of 2,4-diaminopyrimidine 3-oxide claim that it plays a role in the prevention of seasonal alopecia [37]. The emergence of two new products in US propecia and rogaine extra strength (minoxidil) 5%, have brought over a new dimension to treatment options offered by a physician in treating androgenic among men [38].

Eye care cosmeceutics

Over exposure to the computer screen and environmental pollution as well as aging makes the skin under the eye to be thinner, drier and rougher. Hence, the better choice of eye care cosmeceuticals has an ingredient that works from the inside out by interacting with the cells without irritating the eyes. Specially formulated (SPF) products are needed for the skin beneath the eye which lacks subcutaneous fat and no oil glands. These products help to reduce the signs of premature aging and provide protection, moisture to replenish and repair. The main ingredients in marketed eye care creams were vitamin A,C and E, green tea, tiare flower, butcher's broom, chamomile, wheat germ and corn oil, squalene, carrot extract, horse tail, calendula, etc. Some special products contains yeast (main ingredient in one of the marketed product), aosain (algae extract from seaweed), liposomes (smoothening, reducing bags and circles and help to keep brighter and tone), *ginkgo biloba*, cucumber and alpha bisabolol with chamomile.

Lip care cosmeceutics

The skin in lip is extremely thin and unable to moisture themselves. Like eye, some special products are formulated for lips to protect it from the sun and environmental pollutions. While formulating a lip balm with SPF Two main issues to be taken into consideration first is FDA approval for SPF and second is which type of UV protectors used in the formulation. Physical and chemical UV protectors are commonly available. Mostly used one is physical, e.g. Zinc oxide, and titanium dioxide. For a formulation, the ratio of physical UV protector and wax (high-quantity) to be optimum. This is to avoid drying and chalking feeling. Dental care compositions developed by Lawlor is useful for providing a substantive composition that can provide prophylactic, therapeutic and cosmetic benefits on the surfaces of the oral cavity [39].

The concept of complementary or alternative medicine is increasingly becoming more widely accepted, and there is a corresponding rising interest in herbal remedies. Recently, the role of herbal drugs, herbal products, and certain phytochemicals in the control of aging has been shown [40]. There are a number of plants, with antioxidant potentials, which are generally used in common diets and may play a role in treating free radical generated conditions such as sunburn, wrinkles, and ageing. Some of these plants are listed in Table 1 [41-59]. A number of cosmetics manufacturer have incorporated some of the natural antioxidants mentioned earlier in cosmetic formulations. Some examples of these are listed in Table 1.

EFFICACY OF COSMECEUTICALS

Rigorous efficacy studies conducted on pharmaceuticals have brought about expectations on cosmeceuticals. As there have not been enough studies on veterinary cosmeceuticals, these products are being sold as animal treats instead. Despite extensive studies carried out on animals coming out with anti-inflammatory, anti-tumorigenic, anti-microbial, anti-peroxidation and free radical scavenging activities in wide range of models using mouse, rats, and guinea pigs, [60] most of their efficacy remain unproven without conclusive findings. These studies neither intervent phase 2 or 3 clinical trials nor randomized studies that prove their efficacy. The so called better cosmeceuticals have fared worse on rigorous testing. While high concentrations of vitamins C and E do indeed provide protection against ultraviolet skin damage, the low concentrations have not been as effective. [61] Moreover the stability of these vitamins is compromised upon exposure to light and air. [62] Finally, the incorporation of the vitamins into cosmeceuticals as esters or mixtures of isomers are neither absorbed nor metabolized by the skin. Farris, 2005 findings revealed that cosmeceuticals are containing 15% vitamin C also known as skinceuticals, probably have some effect on wrinkles. The term skinceuticals suggest that traditional cosmeceuticals do not contain such a high amount of vitamin C.

TOXICITY OF COSMECEUTICALS

The term 'natural' is frequently used for most components of cosmeceuticals and willingly or unwillingly connotes safety. This is far from the truth. Carbaryl, the only constituent of veterinary cosmeceuticals with documented toxicity profile, has an oral LD_{50} of 100 mg/kg in mice and 250 mg/kg in rats [63]. Though, it is rapidly metabolized by human and animals and does not accumulate, low doses have been known to cause dermal and eye irritation in rabbits despite the dermal LD_{50} in rabbits is quoted as >2000 mg/kg [64]. Vitamin E has been shown to cause a significant increase in contact dermatitis [14] while the antioxidant P-hydroxyanisole increases skin pigmentation [65]. Some component peptides have also been shown to be carcinogenic [14]. Perhaps the greatest danger is from deliberate adulterations and incorporation of harmful products like steroids and retinoid. These can lead to devastating skin and systemic changes [66]. Microbial contaminants have been reported with unfavorable consequences [65].

COMMON MYTHS AND MISCONCEPTIONS [10]

- Cosmeceuticals and cosmetics are regulated as drugs.
- Cosmeceuticals claims in labeling and advertising are substantiated and approved before market.
- Cosmetic ingredients undergo premarket testing and review by the FDA for safety.
- Cosmetic ingredients undergo premarket testing and review by the FDA for efficacy.
- "Natural" products are safer than synthetic.

Table 2: Comparison of drugs and cosmetics in case of regulatory aspects

Serial no.	Drug products	Cosmeceutical products
1	Pre-approval is necessary	No pre-approval is necessary
2	Pre-determined end point according to class of drugs	No pre-determined end point according to active ingredients
3	Safety studies of drugs are important such as animal, toxicology, pharmacokinetic, pharmacodynamics, and drug-drug interactions, etc.	No definition of safety Great latitude of documentation
4	Complex label requirements (chemical structure of active ingredients, formula, strength, additives, indication of use, contra-indications, precautions, warnings, adverse effects, etc.)	Well defined but far less complex
5	Strict control on manufacturing practice and inspections followed	Should follow GMP but not strict
6	Active ingredient and additives must be approved by FDA	Change in formula is a matter of course Not reviewed by FDA
7	Claims are monitored strictly	Claims are seldom monitored No approval for claims
8	Time of drug development is 7-15 years	Development of cosmetic using break-through technology is 3-5 years
9	Cost of new drug development is $ 800 m	Cost of cosmetic development is $ 2-$ 3 m only
10	Pre-market application is must with safety and efficacy studies	Not necessary to do pre-market application

- "Cruelty-free cosmetics" have had no animal testing and are a special noble movement.
- Hypoallergenic means that the product has been tested to remove all allergenic materials and the product will be tolerated by the allergic or sensitive individual.

Regulatory aspects of cosmecutics

Drug products have stringent regulatory requirements. According to regulatory aspects of drug products, cosmeceutical products are compared and tabulated in Table 2.

CONCLUSION

Cosmeceuticals are not drugs but are claimed to have drug-like effects. The claims are largely unsubstantiated and the term, though misleading, has probably come to stay. The term and the target consumers appear flamboyant enough to with stand Government regulations. In future, more effective formulations containing herbal component may come in trend. The addition of herbal extracts for therapeutic use requires better understanding of the herbal potential. The present trend towards herbal cosmetics with effective therapeutic property will continue and may be some newer herbs will also be placed in cosmetics world. In coming future, the regulatory authorities will need to frame some laws concerned with safety, efficacy and quality assessment of these newer herbal cosmeceuticals. In a free trade world, the benefits and adverse effects of cosmeceuticals are probably optimized by frequent review to inform the clinical and public stake-holders of their uses and limitations. An informed public is the best audience to guide the science and art of cosmeceutics toward more formal substantiation if not regulation. Perhaps professional and consumer education would better protect consumers who are trying to make sense of this billion-dollar industry. Physicians are in an especially good position to help patients and potential cosmeceutical users. Understanding that, although scepticism holds value, we may yet find hope in a jar.

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