Cosmeceuticals

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Objectives

• Acquaint with history of cosmeceuticals
• Define the term ‘cosmeceuticals’
• Differentiate the term ‘drug’ versus ‘cosmeceutical’
• Elucidate the ‘Regulatory Policies’ of cosmeceuticals
• Single out the term used for market claims in cosmetics and cosmeceuticals
• Describe the common active contents used in cosmeceutical products

Outline

1. Introduction
2. International Regulatory Policies
3. Classifications
4. Conclusion/Future Directions

Introduction

Drugs
Cosmetics
Cosmeceuticals
"cosmetic” and “pharmaceutical”

Cosmeceuticals: the origin concept

Albert M. Kligman

• The meeting of Society of Cosmetic Chemists
• The response to ‘cosmeceuticals’?
  o Immediate disapproval and even outrage
  o Albert M. Kligman was banded by colleagues as a troublemaker.
  o Generated a huge amount of controversy

Cosmeceuticals: the origin concept

• Cosmeceuticals-topical formulations which were neither pure cosmetics, like lipstick or rouge, nor pure drugs, like corticosteroids.
• Cosmeceuticals: a hybrid category of products lying on the spectrum between drugs and cosmetics.
Cosmeceuticals: the origin concept

- The term 'cosmeceuticals' has permanently entered our vocabulary of skincare products
- Nutraceuticals - products which are similar in perceived benefits but ingested orally
- Aquaceuticals - marine products with drug & cosmetic effect
- Neoceuticals - over-the-counter drugs with cosmetic effects
- Floraceuticals - botanicals with drug and cosmetic effects

Alternative terms for cosmeceuticals have also appeared, including
- Performance cosmetics
- Functional cosmetics
- Dermaceuticals
- Active cosmetics
- Nutricosmetics

International Regulatory Policies

Cosmetic : EU

- A 'cosmetic product' shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body epidermis, hair system, nails, lips and external genital organ or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition.

Cosmetic : Japan

- The term cosmetic means any article intended to be used by means of rubbing, sprinkling or by similar application to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance of the human body, and for keeping the skin and hair healthy, provided that action of the article on the human body is mild.

International Regulatory Policies

the US, Europe and Japan

Cosmetic : EU

- The product information that must be made available to administration includes the following:
  - Qualitative and quantitative composition of the product
  - Specifications of raw materials
  - Methods of manufacture
  - Safety assessments
  - Proof of effectiveness

International Regulatory Policies

Cosmetic : Japan

- The term cosmetic means any article intended to be used by means of rubbing, sprinkling or by similar application to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance of the human body, and for keeping the skin and hair healthy, provided that action of the article on the human body is mild.
International Regulatory Policies

Cosmetic : Japan
- Authorities in Japan have created their own laws in response to the problem that many skin-care products are neither pure drugs nor pure cosmetics in the traditional sense, but are mixtures or hybrids of the two.
- Cosmeceuticals are called “quasi-drugs” in Japan.
- They allow cosmetics to include pharmaceutically active ingredients, provided that the medicinal effects are mild and the products have been demonstrated to be safe.

International Regulatory Policies : US

Drug
- An article intended for use in the diagnosis, mitigation, treatment, or prevention of disease or intended to affect the structure or any function of the body

Cosmetic Product
- An article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any parts of thereof for
  - Cleansing
  - Beautifying
  - Promoting attractiveness
  - Altering the appearance without affecting structure or function

International Regulatory Policies

the US
- In the US, the following agents are regulated as drugs while they are sold as cosmetics in Europe:
  - Antiperspirants
  - Antidandruff shampoos
  - Sunscreens

International Regulatory Policies

Cosmeceuticals : US
- A subclass of drugs

Cosmeceuticals : EU & Japan
- A subclass of cosmetics

The regulations of cosmeceuticals have not been harmonized between the USA, European, Asian and other countries.

Thailand → ‘controlled ingredient’
International Regulatory Policies

**International Regulatory Policies**

- **Cosmetics**
  - No extensive testing like drugs
  - Less-time consuming and cost
  - Prohibit the false advertisements

- **Cosmeceuticals**
  - Cosmeceuticals are not regulated by the U.S. FDA
  - are not subject to premarket requirements for proof of safety or efficacy.
  - The rigorous testing required for pharmaceuticals is not mandatory for cosmeceutical products.

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**International Regulatory Policies**

**Classifications**

- A cosmeceutical : an ingredient with medicinal properties
  - Antiinflammatories/Botanicals
  - Hydroxy acids
  - Pigmentlightening agents.
  - Antioxidants

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**Classifications:** Antioxidants

- Antioxidants neutralize damaging free radicals thus protecting cells from both Endogenous stress -byproducts of cellular energy Exogenous stressors-UV light, pollution, cigarette smoke
- Antioxidants comprised a group of diverse molecules including(but not limited to),
  - Coenzyme Q-10 (CoQ-10)
  - Idebenone
  - Polyphenols
  - Alpha lipoic acid (ALA)
  - Vitamins (A, B, C, E)

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**Conclusion/Future Directions**

- The U.S. cosmeceutical market
  - 2001: $2.8 billion
  - 2005: $12.5 billion
  - 2010: $16 billion
- Hundreds of products are marketed to diminish fine lines and wrinkles, decrease redness, smooth texture, fade discoloration, and give a more youthful appearance to the skin.
Conclusion/Future Directions

- Consumer-driven demand has lead to development of products to counteract the signs of aging skin, to decrease erythema, and to even out tone and pigmentation.
- These cosmeceuticals can help protect the skin from photodamage and in some ways repair it through stimulation of new collagen production.
- With different cosmeceuticals being touted to impart different effects, an upcoming trend will be the multifunctional cosmetic.
- Future research in wound healing and biotechnology will serve to expand this field.

References