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Evaluation of the Functional Cosmetics

Mi-Ok Yun,

Cosmetics Evaluation Team, Drug Evaluation Department
Korea Food & Drug Administration

Cosmetics have mild activity on the human body, and intended to be used for cleaning, beautifying the human body, and also keeping healthy skin or hair, promoting attractiveness or altering the appearance. Functional cosmetics, in other words cosmeceuticals, are restricted for following functions: 1) Whiten the skin tone by preventing deposition of melanin pigmentation or lightening of the color of melanin of skin, 2) alleviate or improve wrinkles of the skin, and 3) protect the skin from the ultra violet rays from the sun. According to the functions of the functional cosmetics, skin whitening products, anti-wrinkle products, and suntan & sunscreen products are manufactured.

In order to manufacture and import the functional cosmetics in Korea, the approval process in KFDA is necessary. The review process in KFDA is performed based on The Korea Food and Drug Administration Notification 2007-44, "The Regulation of Reviewing the Functional Cosmetics" (June 29, 2007). Only after the approval of KFDA, functional cosmetics are allowed to advertise to the consumers for their functionality.

Key words : functional cosmetics, whitening, anti-wrinkle, sunscreen

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by Mi-Ok Yun

Cosmetics Evaluation Team
Drug Evaluation Department
Korea Food & Drug Administration

What is cosmetics ?

- **Mild action on the human body**
- **Cleaning,**
- **Beautifying**
- **Adding to the attractiveness**
- **Altering the appearance**
- **Keeping or promoting the skin or hair in good condition**

What is functional cosmetics?

☐ Skin Whitening Products

- Product intended to help whitening of skin by preventing melanin pigmentations, freckles and spots on skin
- Product intended to help whitening of skin by thinning the color of melanin already pigmented.

☐ Anti-Wrinkle Products

- Product intended to alleviate the wrinkles by firming skin

☐ Suntan & Sunscreen Products

- Product intended to maintain well sun-tanned skin by preventing from strong sunlight,
- Product intended to protect skin by blocking or dispersing the UV rays.

Regulations related to Functional Cosmetics

Regulations	established by
Cosmetic law	National Assembly
Enforcement regulation of the cosmetic law	Ministry of Health and Welfare
The regulation of reviewing the functional cosmetics	KFDA
Measurement standard for UV protection efficacy	KFDA
Korean functional cosmetics codex	KFDA

Guidelines related to Functional Cosmetics

Guidelines	established by
Guideline for efficacy evaluation of functional cosmetics (I)	KFDA(2003)
Guideline for efficacy evaluation of functional cosmetics (II)	KFDA(2005)
Guideline for Evaluating Sunscreen Product Water Resistance	KFDA(2007)

Review of the Functional Cosmetics

Safety and Efficacy Data

- Safety Data
- Efficacy Data
- Data on origin/background of discovery/development

Specification and test methods

Safety Data

- Single dose toxicity
- Primary skin irritation test
- Ocular irritation or mucous membrane irritation test
- Skin sensitization
- Photo-toxicity and photo-sensitivity
- Human Patch test

Efficacy Data

- Dossier related to effectiveness(Non-Clinical trials)
 - tested by Korean or foreign professional institution
 - prove the active ingredient's working mechanism to human body by in vitro method
- Dossier which prove the efficacy when applied to human body(Clinical trials)
- Dossier for SPF(Sun Protection factor) and/or PA(Protection grade of UVA) if the product for Designed to protect the skin from UV rays of the sun

Specification and test method

- Identification of the active ingredient
- Assay for the active ingredient
- Functional Test
 - *in vitro* SPF test,
 - Whitening efficacy test,
 - Wrinkle alleviation test, etc.

Exemption of data submission

- Functional cosmetics containing the materials listed in KFDA notification (No. 2006-12)
 - exemption : Safety data
- The Regulation of reviewing the Functional cosmetics (Notification No. 2007-17) Annex 4.
 - exemption : Efficacy data
- Korean functional cosmetics codex(Notification No. 2007-44)
 - exemption : Specification and test methods

Evaluation of Skin whitening effects



Guideline for Efficacy Evaluation of Skin Whitening Cosmetics

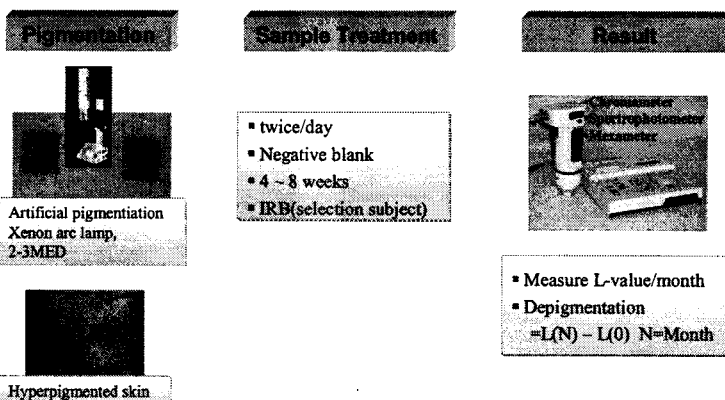
In vitro efficacy test

- Tyrosinase activity inhibition assay
- DOPA auto-oxidation inhibition assay
- Melanin synthesis inhibition Assay with melanocyte

Clinical test

- Efficacy evaluation on induced pigmentation
- Efficacy evaluation on hyper melanosis

Clinical Test



Schema of clinical test for depigmenting effect

Evaluation of Anti-wrinkle effects



Guideline for Efficacy Evaluation of Anti-wrinkle Cosmetics

***In vitro* efficacy test**

➤ **Collagen synthesis assay**

➤ **Collagenase inhibition assay**

Clinical test

➤ **Assay wrinkle with silicone replica and image analysis**

Clinical test

Using the Silicon Replica and Image Analysis



Evaluation of Sun Protection Effects

☐ UVB Protection(SPF Measurement)

- Korean Measurement Standards for UV Protection Efficacy (KFDA)
- International Sun Protection Factor (SPF) Test Method (COLIPA, JCIA, South Africa)
- Sunscreen Drug Products for Over-The-Counter Human Use(US FDA)
- Sunscreen Products-Evaluation and Classification (AS/NZ)

☐UVA Protection(PA Measurement)

- Korean Measurement Standards for UV Protection Efficacy (KFDA)
- Japan Cosmetic Industry Association Measurement Standard for UVA Protection Efficacy (JCIA)

☐Labelling

- UVB : SPF 25 or SPF 50+
- UVA : PA+, PA++, PA+++
- Water resistance and Very water resistance

Monitoring on Adverse Effect

- Erythema
- Edema
- Scaling
- Itching
- Stinging
- Burning
- Tightness
- Prickling

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Approval by KFDA

