Regulations concerning the Supervision and Administration over Cosmetics (Draft)

化妆品监督管理条例

China Food and Drug Administration (CFDA)

Translated by Chemlinked

Release Date: 2014/11/08

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Regulations concerning the Supervision and Administration over Cosmetics (second draft version)

Chapter I General Provisions

Article 1 (Legislative Purpose) The purpose of enactment of this Regulation is to regulate production and operation of cosmetics, strengthen supervision and administration of cosmetics, ensure quality and safety of cosmetics..

Article 2 (Scope) In the territory of People's Republic of China, the research, production, operation, supervision and administration of cosmetics shall comply with this Regulation.

Article 3 (Definition of Cosmetics) In this Regulation, cosmetics refer to products intended to be applied on the surface of human body (such as skin, hair, nails, lips etc.), teeth and oral mucosa by spreading, spraying or other similar ways for the purpose of cleansing, protecting, beautifying or grooming skin or maintaining the good condition of skin.
The CFDA is responsible for formulating and publishing the cosmetic product catalog. .

Article 4 (Assignment of Responsibility) China Food and Drug Administration is responsible for the supervision and administration of cosmetics in China. The relevant departments of the State Council are responsible for the supervision and administration of cosmetics within their respective areas of responsibility.
The food and drug administration departments of local people's governments above the county level are responsible for the supervision and administration of cosmetics within their respective administrative areas. The relevant departments of local people's governments above the county level are responsible for the supervision and administration of cosmetics within their respective areas of

responsibility.

Article 5 (The First Basic Principle: the principle of main liability of manufacturers) Cosmetics manufacturers and operators shall comply with laws, regulations, standards and guidelines in the process of production and operation activities, strengthen management, keep credibility and self-discipline and ensure the quality and safety of cosmetics.

The state encourages and supports cosmetic manufacturers and operators to adopt the standards of advanced technology and management to improve the quality and safety of cosmetics.

Article 6 (The Second Basic Principle: the principle of industry self-discipline) Cosmetics Industry Association shall strengthen industry self-discipline, supervise and guide cosmetics manufacturers and operators to comply with laws, regulation, standards and guidelines in the process of production and operation activities to promote the development of the industry credibility system.

Article 7 (The Third Basic Principle: social supervision) Any organizations and individuals are able to supervise cosmetic manufacturers and operators and report any activities done by cosmetics manufacturers and operators which violate this Regulation. Where the serious violation of laws is substantiated, the CFDA shall disclose them to the public though media according to the law.

Chapter II Ingredients and Products

Article 8 (Cosmetic Ingredient Management) The state practises inventory management for cosmetic ingredients. The CFDA is responsible for the formulating and publishing the inventories of prohibited cosmetic ingredients, restricted cosmetic ingredient and permitted cosmetic ingredients. The inventory of permitted cosmetic ingredients includes preservatives, sunscreens, colorants, hair dyes, whitening agents and other high risk ingredients.

Where the inventories need to be adjusted, the CFDA shall publish them to the

public in a timely manner and re-publish the updated inventories by the end of each year.

Article 9 (New Ingredients) New cosmetic ingredient refers to the natural and artificial ingredient used in cosmetics for the first time.

For new preservatives, sunscreens, colorants, hair dyes, whitening agents and other high risk ingredients, domestic manufacturers or agents designated by the importer are responsible for applying to the CFDA. After approval, the ingredient can be used.

For those new ingredients outside the mentioned scope, domestic manufacturers or China agents designated by the importer shall file a record with the CFDA within 30 working days before use, submitting related dossiers in accordance with the technical record filing requirement prescribed by the CFDA. Where there are any objections in the departments of the CFDA, the objections shall be raised within 30 working days after record filing.

Within 10 working days from the approval or successful record filing the CFDA shall publish the relevant information to the public. Any organization and personnel are able to raise their objections to the CFDA. Where the objection is established, the CFDA shall withdraw the approval and notify the manufacturers and agents.

Article 10 (Usage Report of New Ingredient) Where the new ingredient is approved or filled, the domestic manufacturers or agents designated by the importer shall report the usage and safety situation to the CFDA every half a year within 3 years.

Article 11 (Cosmetics Classification) Cosmetics are divided into general cosmetics and special cosmetics.

Special use cosmetics include hair dyes products, hair perming products, whitening products, sunscreens and other special cosmetics deemed by the CFDA.

General cosmetics are those cosmetics except for special cosmetics

According to the usage of products, cosmetics are divided into special use cosmetics and non-special use cosmetics.

The catalog of special cosmetics shall be formulated and promulgated by the

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