Available online on 15 Dec, 2020 at https://ijdra.com/index.php/journal

International Journal of Drug Regulatory Affairs

Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with Delhi Pharmaceutical Sciences & Research University

Review Article

Cosmetics in US and India: Overview of Regulations and Registration process

Abhimanyu Rampal*, S P Yamini Kanti

Dept. of Applied Chemistry, Amity University Noida Sector-126, Uttar Pradesh, India 201301

Abstract

Cosmetics, for a long period of time have been used as beauty products for the care of body and face which eventually enhances a person's appearance. These products are usually constituted from a mixture of different chemical compounds which are synthetic as well as organic in nature. For a long period of time, these products have not come under the ambit of regulatory authorities and have gone through the markets unchecked. The way a drug manufacturing and sale process is monitored by the regulatory authorities across the world, which includes careful monitoring of clinical trials, scrutinizing research results like safety, efficacy and quality of a drug has been avoided for a long period of time in case of parameters related to cosmetics. Some groups alleged that the industry practices are flawed, that there is little government regulation, and that cosmetics contain cancer-causing chemicals and other toxicants which are harmful for human body. Rules have certainly changed over time and major countries like India have started following guidelines while giving regulatory approval to cosmetics just like USA. The U.S. (FDA) functions include the banning and restriction of ingredients for safety purposes. The Cosmetic Ingredient Review (CIR) which is an independent review board that critically evaluates chemical ingredients used in cosmetics and publishes results of its findings. Similarly in India, CDSCO (Central Drugs Standard Control Organisation) and DCGI (Drug Controller General Of India), both are responsible for evaluating the composition of cosmetic products and their safety while referring to a drafted set of guidelines known as BIS(Bureau of Indian standards) guidelines. The article focuses on various aspects considered by USA and India while giving regulatory approval to cosmetic products.

Keywords: Cosmetics, US FDA, Cosmetic Ingredient Review (CIR), CDSCO

Article Info: Received 28 Oct. 2020; Review Completed 02 Dec. 2020; Accepted 13 Dec. 2020

Cite this article as:
Rampal A, Yamini Kanti SP. Cosmetics in US and India: Overview of Regulations and Registration process. Int J Drug Reg Affairs [Internet]. 15 Dec.2020 [cited 15 Dec.2020]; 8(4):20-24. Available from: http://ijdra.com/index.php/journal/article/view/430

DOI: 10.22270/ijdra.v8i4.430
*Corresponding author Tel.: +91-9953402923;
E-mail address: abhimanyurampal5@gmail.com (Abhimanyu Rampal).

1. Introduction

Cosmetics available under these different categories, each constituted for different purposes and different characteristics.

Cosmetics designed as skin care products can be used to clean and exfoliate, as well as replenish skin, through cleansing agents, toners, balms etc. cosmetics designed for personal care, such as shampoos, body shower, scrubs etc. can be used to cleanse the body. (1) Cosmetics designed to accentuate one's appearance (makeup) are used to conceal blemishes, enhance natural features (like eyebrows and eyelashes), and add texture to a person's face. Cosmetics are also designed to add fragrance to the body. (2)

Role of cosmetic industry in evaluating safety of products

Although regulatory authorities like US FDA in United States of America and CDSCO in India play an important role in the management commerce of cosmetics along with review of product's composition by a scientific board, it is the cosmetic companies who are majorly responsible to ensure that the quality and the safety of the finished products is at acceptable standards for its customers. (3) Safety tests are necessary and mandatory to get approval for sale of cosmetics in both the countries. Cosmetic companies majorly strive to achieve this through several test procedures,

1. Including industry standards for good manufacturing practice (GMP) which is issued by a legal authority,

2. Use of ingredients that are under permissible limits and have undergone safety testing,

3. Worldwide regulatory standards and (d) continuous testing of new ingredients also. (4, 5)

US FDA

The U.S. FDA, Centre for Food Safety and Applied Nutrition (CFSAN) is the primary body of the

government that looks after programs and policies related to safety and use of cosmetic products. The FDA has jurisdiction over 1. Cosmetic products and their ingredients; 2. Labelling requirements and claims, which is an important source of information for the consumers; 3. Specific guidance on recall policy; and 4. Bans on non-permissible ingredients. Specifically, the FDA has the authority over:

- prosecuting violators
- Coordination manufacturers to execute product recalls
- seizing illegal products
- making warning labels mandatory on products
- Inspection of facilities that manufacture cosmetics
- Restriction of non-permissible ingredients due to safety concerns
- issuing warning letters

The Federal Food, Drug, and Cosmetic Act (FD&C) is an important law for cosmetic products marketed in the USA. It prohibits marketing of cosmetic products which have certain amount of adulteration and also keeps track of violations involving cosmetic ingredients, adulterants, processing, packaging, shipping and handling. The law states that cosmetic products are branded as adulterated if it contains any poisonous substance, which may pass on its ill effects to users under the conditions of use mentioned in the labeling. (6) This statement places responsibility of safety directly upon the cosmetic company, and it is mandatory for industry members to ensure safety to buyers. The Federal government does not require cosmetics to acquire premarket approval or any specific regulatory testing, such as that required for drugs and medical devices. However, if a company fails to submit adequate testing procedures which includes evaluation of safety protocols of a cosmetic product or its ingredients before marketing, the regulatory approval for commerce won't be granted. (7)

There are certain chemical ingredients that the FDA has recognized as hazardous for consumer safety which should not be put in cosmetic products. (7) Such restricted ingredients are mentioned below:

- Mercury promotes neurotoxicity.
- Zirconium-contains complexes and aggravates respiratory diseases
- Bithionol, which has photosensitization potential.
- Methylene chloride promotes tumorigenicity in laboratory animals.
- Vinyl chloride affects the central nervous system and is carcinogenic in nature.
- Chloroform, as it promotes liver tumours in rodents due to lifetime oral ingestion
- Additional colour additives must also be tested for safety by cosmetic or dye manufacturers and subsequently acquire approval by the FDA. Thus, it should be clear that the FDA has a vital and significant role in the overall safety evaluation and monitoring of cosmetic ingredients and products. (7)

2. Registration process in US

CIR

An extension of the US FDA body, Cosmetic Ingredient Review (CIR) has been responsible for evaluating and suggesting the harmful effects caused by certain ingredients present in the cosmetic products since its establishment in 1976. The CIR expert panel includes scientists who are publicly nominated by consumer, medical and scientific community, government agencies and cosmetic industry. They thoroughly review and assess the safety of certain ingredients being used in cosmetics and publish these observations along with concrete results in reputed journals in a free and fair manner which is also coherent with the guidelines. The extent to which a consumer can be exposed to a certain ingredient with a specific quantity present in the final product is considered along with its mechanism and biological activity on or in the body after application. The organisation carries intensive literature review and presents its observations based on its findings. (8) Parameters on which these observations are based are as follows:

- absorption, distribution and metabolism
- animal toxicology test data which includes acute, short-term, sub chronic and chronic studies,
- in vitro analysis
- physical and chemical properties of the composition

Presence of any clinical data on the final product is also assessed and if any deficiencies are found then the panel makes sure that those are reported along with data on hazardous ingredients present in the product. After conducting a fair process and reviewing scientific literature, the ingredients that are found to have questionable activity will be published in the International Journal of Toxicology, a publication of the American College of Toxicology.

Although there are specific chemical compound that are banned by the US FDA but limited concentration of these compounds are permitted for use in cosmetic products by the CIR. There are hundreds of ingredients in the CIR database on which limited amount of information has been gathered over the years and there are substantial gaps that can be filled by extensive research so that these ingredients can be used in a specific concentration in the final product. (8) The CIR has conveyed to the industry that they should come in forefront and acquire data on the safe use of such ingredients. Transparency in the testing process followed by the industry and publication of findings in a fair manner would reduce a lot of confusion about the nature of ingredients and the approval process will be streamlined.

List of ingredients is checked. None should be included from the non-permissible

Figure 1. Registration process in US

List of certain key ingredients which are prohibited

- Methylene chloride
- Bithionol
- Hexachlorophene
- Vinyl chloride
- Mercury compounds
- Zirconium complexes

Labeling requirements according to the FDA

- Nature and the use of product should be justified by a product description either by the name through a short descriptive introduction. It must be in English and should be understood by public
- The contents present in the product should be specified on the label accurately in terms of weight and numerical count
- Name and address of the manufacturer or distributor should be mentioned on the label.
- Directions for use for the product should be mentioned in clear sentences along with any necessary warnings and caution statements

3. Indian Legislation

The Indian cosmetics market is the fastest growing in the world with dynamic changing regulation which represents a positive growth for the industry .The nature of the regulatory scenario provides further opportunities for business. Cosmetic guidelines are governed by Drugs and Cosmetics Act, and the official government body is CDSCO (Central Drugs Standards Control Organization) headed by Drugs controller general of India. Local manufacturing of cosmetics is governed by state regulatory authorities. (9)

To get marketing approval for cosmetic, the products must comply and be coherent with BIS (Bureau of Indian Standards) guidelines which are put forward by CDSCO to ensure safety of consumers. The BIS has recognized and classified raw materials and adjuncts in terms of safety. The following 4 classifications are

- GRAS List - Ingredients which are safe and can be used in permissible concentration.
- GNRAS List Ingredients which are not safe and are prohibited to be used in any form
- Preservatives Ingredient which stops bacterial or microbial growth thus preventing the product from getting spoilt in normal atmospheric conditions
- U.V. Filters - Substances used in cosmetic products which are intended to protect skin from certain UV rays

Table 1. Concentration of heavy metals that is considered permissible according to BIS in case of finished products

Heavy metals	Specification	Test Methods
Mercury	Less than 1 ppm	CTFA
Lead	Less than 20 ppm	CTFA
Arsenic	Less than 2 ppm	CTFA
Other heavy metals	Less than 100 ppm	CTFA

Certain documents are required to get regulatory approval for marketing of cosmetic products. These should be according to BIS guidelines and have separate functions and importance. The following documents are:

- COAs- These are certificate of analysis of the products having parameters like colour, odour, appearance, pH, specific gravity, microbial count, heavy metal count etc. All these parameters should be in range and coherent

with the regulatory guidelines. It is the responsibility of the manufacturer to conduct all these tests through a certified lab.

- INCIs- This is the ingredient list of the products which specifies chemical used along with their weight percentage in descending order. The total percentage should come out as 100.
- Heavy metal, non-animal declarations are also required to be submitted by the company.
- Testing methods report which have a brief write-up mentioning the procedure followed to measure all the parameters used while testing the products in the lab like pH, viscosity, heavy metals present, microbial count etc.
- Labels and artworks with information of the product along with description and directions of safe use, complete name and address of the manufacturer, pack size and ingredient list.
- Manufacturing license and a certificate of valid GMP.
- Import registration number in case of imports.

4. Registration process in India

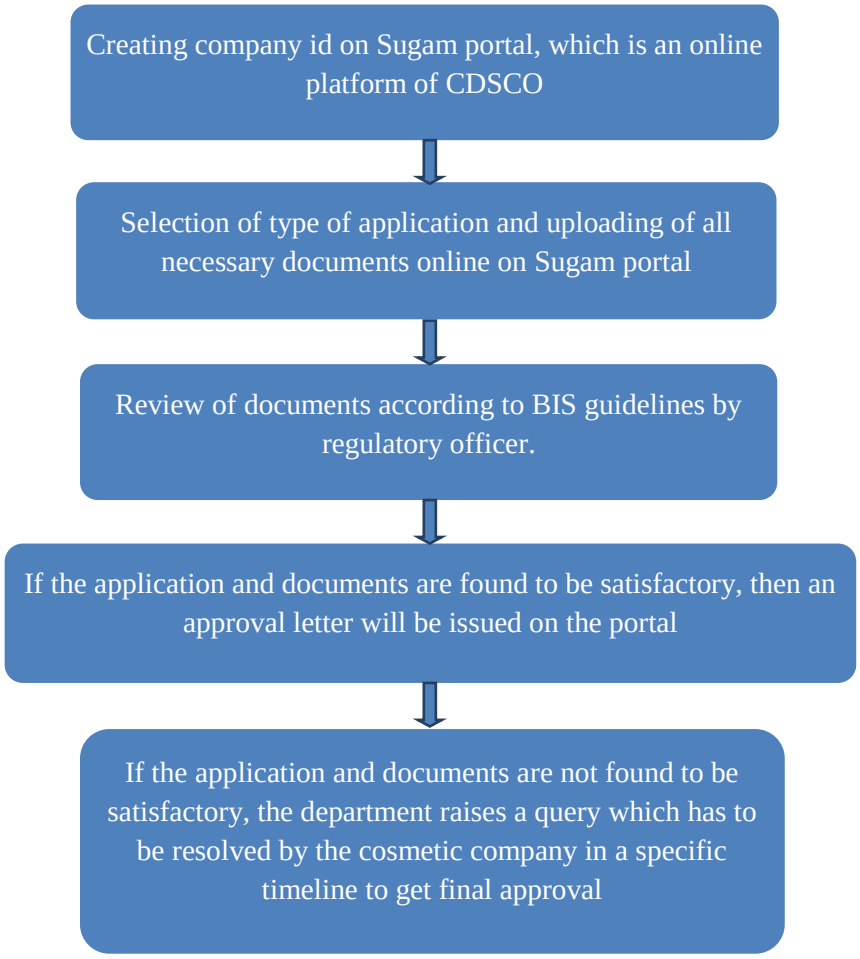

Figure 2. Registration process in India

Table 2. Comparison of requirements in US and India

Requirements	US	India
Agency	FDA	CDSCO
Regulation	Food, Drug and Cosmetics Act	Drugs and Cosmetics Act
Pre-market approval	Not Required	Required from state authorities
Safety	Responsibility of manufacturer	Manufacturer is asked to maintain records and furnish valid COAs and INCIs
Labeling declarations	FDA 21 CFR 701 & 740	According to BIS
Label language	English	English
Evaluation of ingredients safety	By CIR	By CDSCO

5. Conclusion

The cosmetic products may present health risks and adverse effects due to presence of toxic substances commonly found in product formulations. Earlier there was no robust mechanism or legislation present to ensure that the ingredients used in such formulation are safe and a public health crisis can be avoided. In certain recent times, countries like India and USA have put forward certain guidelines and regulations that ensure thorough analysis of documents and scrutiny of contents of the cosmetic products. This strategy would ensure public health safety and would also fix accountability of private players. There are still some voids and gaps that can be filled to streamline and make the process more credible and reliable but that needs further research into this subject and study of various regulations and laws followed in different parts of the world. (10,11)

Acknowledgements

We would like to express our sincere gratitude to International Journal of Drug Regulatory Affairs for their continuous support and guidance.

Financial Disclosure statement: The author received no specific funding for this work.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

References

1. Malik.V. The Drug and Cosmetics Act, 1940. 18th Edition. New Delhi: Eastern Book Company; 2007. p. 5-6.
2. Draelos ZD. Cosmetics: The Medicine of Beauty. Journal of Cosmetic Dermatology. 2015;14 (2):91
3. Gerberick, G. F, and Robinson. M.K. A skin sensitization risk assessment approach for evaluation of new ingredients and products. Am. J. Contact Dermatitis. 2000;11:65–73.
4. Gerberick, G. F., Robinson.M.K and Stotts. J. An approach to allergic contact sensitization risk assessment of new chemicals and product ingredients. Am. J. Contact Dermatitis. 1993; 4:205-211.
5. Robinson. M. K., Stotts.J, Danneman.P.J and Nusair.T.L. A risk assessment process for allergic contact sensitization. Food Chem. Toxicol. 1989; 27:479-489.
6. CFSAN/Office of Cosmetics and Colors. FDA Authority over Cosmetics. CFSAN [Internet].US FDA; 2005 [cited 2020 Aug 03]. Available from: https://www.fda.gov.
7. 21 CFR Volume 17, 2002. Code of Federal Regulations, Title 21, Volume 7. Chapter 1-Food and Drug Administration. Department of Health and Human Services. Subpart B-Requirements for Specific Cosmetic Products; 2002
8. Cosmetic Ingredient Review: General Information. Accessed [Internet]. CIR;2005 [cited 2020 Aug.03]. Available from: www.cir-safetv.org
9. Drugs & Cosmetics Act 1940 [Internet]. CDSCO; 1940 [cited 2020 Apr.10]. Available from: https://cdsco.gov.in/
10. Shaik Md. ZH, Shiva J, Venkateswarlu G, Suthakaran R, Ghouse S. Intellectual Property Right in India- A Review. Int J Drug Reg Affairs [Internet]. 2019 Sep.17 [cited 2020 Sept.22]; 7(3):8-13. Available from: http://ijdra.com/index.php/journal/article/view/327
11. Saddik P, Pappan J. Differentiation between the Regulatory paths placed on Mouthwashes in the US and EU. Int J Drug Reg Affairs [Internet]. 2018 Jun.15 [cited 2020 Sept.21]; 6(2):8-13. Available from: http://ijdra.com/index.php/journal/article/view/229