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COMPARATIVE STUDY OF THE REGULATORY FRAMEWORK FOR COSMETICS AND COSMECEUTICALS IN INDIA VS USA

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ABSTRACT

The global cosmetics and cosmeceuticals market is undergoing rapid regulatory transformation driven by increasing consumer awareness, technological advancement, and stronger safety oversight. This review compares the regulatory frameworks governing cosmetics and cosmeceuticals in India and the United States, with emphasis on definitions, licensing, import registration, labelling, safety substantiation, stability requirements, adverse-event reporting, GMP, and recent legislative reforms. In India, the Cosmetics Rules, 2020, along with subsequent amendments, have strengthened regulatory clarity for manufacture, import, labelling, and safety compliance. In the United States, the Modernization of Cosmetics Regulation Act of 2022 has introduced major reforms, including facility registration, product listing, serious adverse-event reporting, safety substantiation, recall authority, and GMP requirements. The review highlights key similarities, differences, and emerging areas of regulatory convergence between both jurisdictions.

Keywords: Cosmetics regulation, CDSCO, FDA, MoCRA 2022, Cosmetics Rules 2020, cosmetovigilance

INTRODUCTION

The cosmetics industry represents one of the most dynamic and rapidly expanding sectors of the global consumer economy. Growth in this sector is being driven by advances in formulation science, rising disposable income, increasing consumer awareness, digital marketing, e-commerce expansion, and the growing association of cosmetics

with personal care, wellness, hygiene, and preventive self-care. In India, the cosmetics market was estimated at USD 21.50 billion in 2025 and is projected to reach USD 43.85 billion by 2033, growing at a CAGR of 9.3% from 2026 to 2033 **[1]**. Similarly, the United States remains one of the most influential cosmetic markets globally, with its regulatory framework often serving as a reference point for emerging and developing markets **[2]**.

Unlike pharmaceuticals and foods, cosmetic regulation occupies a distinct regulatory space because cosmetics are intended for routine application to the human body for cleansing, beautifying, promoting attractiveness, or altering appearance. However, despite their non-therapeutic intent, cosmetics may be applied directly to sensitive sites such as the skin, hair, scalp, lips, eyes, nails, and oral cavity. Therefore, regulatory systems must ensure that cosmetic products are safe, labelled, free from prohibited or harmful substances, manufactured under hygienic conditions, and supported by adequate quality and safety data **[3, 4]**.

The emergence of the term "cosmeceutical" has further complicated cosmetic regulation. Cosmeceuticals are generally understood as products that lie between cosmetics and drugs because they are marketed with claims suggesting biological, physiological, or drug-like effects. However, neither India nor the United States recognizes "cosmeceutical" as a separate statutory category. In the United States, the Food and Drug Administration clearly states that the term "cosmeceutical" has no legal meaning under the Federal Food, Drug, and Cosmetic Act. Therefore, a product is regulated either as a cosmetic, a drug, or both, depending on its intended use, composition, and claims. This distinction is especially important for products claiming anti-ageing, skin-lightening, anti-acne, hair-growth, anti-dandruff, or therapeutic benefits, where inappropriate claims may shift the product from a cosmetic category to a drug category **[5, 6]**.

India and the United States follow different regulatory philosophies in the control of cosmetic products. India has traditionally followed a more licence- and registration-based system, especially for the manufacture and import of cosmetics. The Cosmetics Rules, 2020, issued under the Drugs and Cosmetics Act, 1940, created a dedicated regulatory framework for cosmetics and consolidated provisions related to import registration, manufacture, labelling, testing, licensing authorities, and regulatory oversight [3]. The Central Drugs Standard Control Organisation is responsible for functions such as scrutiny of applications for registration and import of cosmetic products, amendments relating to registration and import, and issuance of

clarifications or no-objection certificates for cosmetic imports **[7]**.

The Cosmetics (Amendment) Rules, 2025 introduced changes related to terminology, procedural clarity, labelling-related interpretation, and regulatory enforcement. For example, the amendment clarified expressions such as "use before" and "date of expiry" and replaced the term "controlling officer" with "Controlling Authority" for consistency across the Rules **[8]**. In contrast, the United States historically relied more heavily on manufacturer responsibility and post-market surveillance, with limited pre-market approval requirements for cosmetics, except for certain color additives. Under U.S. law, cosmetic products and ingredients generally do not require FDA pre-approval before marketing; however, manufacturers are responsible for ensuring that their products are safe, properly labelled, and compliant with applicable restrictions. This approach changed substantially with the enactment of the Modernization of Cosmetics Regulation Act of 2022, which represents the most significant reform of U.S. cosmetic law in decades **[9, 10]**.

Comparative analysis of definitions in India Vs. U.S.A.

Definition under Indian law

Under Section 3(aaa) of the Drugs and Cosmetics Act, 1940, a cosmetic is defined as any article intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering appearance, including any component used in such products. This definition continues under the Cosmetics Rules, 2020, which provide a dedicated framework for cosmetic import, manufacture, licensing, labelling, testing, standards, and regulatory control **[11, 12]**.

Definition under the U.S. law

Under the Federal Food, Drug, and Cosmetic Act, 1938, as amended by the Modernization of Cosmetics Regulation Act of 2022, cosmetics are defined according to their intended use. The Act defines cosmetics as articles intended to be rubbed, poured, sprinkled, sprayed on, introduced into, or otherwise applied to the human body or any part of it for cleansing, beautifying, promoting attractiveness, or altering appearance **[13]**. A product may be regulated as a cosmetic, a drug, or both, depending on its intended use and consumer perception **[14, 15]**.

The FDA follows an intended-use and claims-based approach for classification. Products claiming only cleansing, beautifying, attractiveness-enhancing, or appearance-altering effects are generally regulated as cosmetics, whereas products claiming to treat, prevent, mitigate, or affect the structure or function of the body may be regulated as drugs or cosmetic-drug combinations **[16]**. MoCRA has expanded

FDA authority over cosmetics by introducing new requirements such as facility registration, product listing, serious adverse-event reporting, safety substantiation, record access, recall authority, and future GMP requirements; however, it has not created a separate statutory category for cosmeceuticals **[17]**.

Comparative analysis of regulatory authorities in India Vs. U.S.A.

India: CDSCO and State Licensing Authorities

In India, cosmetic regulation follows a dual structure involving central and state authorities. The Central Drugs Standard Control Organisation (CDSCO), under the Ministry of Health and Family Welfare, is the principal national authority for cosmetic import regulation and implementation of the Cosmetics Rules, 2020, while the Drugs Controller General of India acts as the Central Licensing Authority for import registration and related approvals **[18, 19]**. State Licensing Authorities regulate domestic manufacture and sale of cosmetics, including licensing and compliance monitoring, whereas the Bureau of Indian Standards supports the framework by prescribing standards for cosmetic products and ingredients **[20, 21]**. The Cosmetics Rules, 2020, effective from 15 December 2020, replaced the earlier cosmetic provisions under the Drugs and Cosmetics Rules, 1945 and introduced a dedicated framework covering import registration, manufacture, labelling, testing, prohibited cosmetics, standards, inspection duties, and laboratory functions.

USA: FDA and Office of Cosmetics and Colors

In the United States, cosmetics are regulated mainly by the FDA under the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and MoCRA 2022. The FDA's Office of Cosmetics and Colors oversees cosmetics and color additives marketed in the country **[22]**. Traditionally, U.S. cosmetic regulation relied on manufacturer responsibility and post-market surveillance, with no routine pre-market approval except for certain color additives. However, MoCRA expanded FDA authority by introducing facility registration, product listing, safety substantiation, serious adverse-event reporting, record access, recall authority, and future GMP requirements. To support MoCRA implementation, the Office of Cosmetics and Colors was moved from CFSAN to the Office of the Chief Scientist in 2024, with the reorganization becoming effective from 1 October 2024 **[23]**.

Evolution and current framework of regulations in India

Cosmetic regulation in India: Historical background

Cosmetic regulation in India originated with the Drugs and Cosmetics Act, 1940, which

provided a unified legal framework for the import, manufacture, distribution, and sale of drugs and cosmetics. The Drugs and Cosmetics Rules, 1945 subsequently operationalized cosmetic regulation by prescribing requirements for labelling, manufacturing standards, quality control, and market compliance. Initially, the framework focused mainly on preventing adulterated, misbranded, and spurious cosmetics, but it gradually evolved to address ingredient safety, microbial contamination, colour additives, consumer labelling, product testing, restrictions on hazardous substances such as hexachlorophene, prohibition of animal-tested cosmetics after 13 October 2014, and concerns related to heavy metals and mercury-containing compounds **[24]**.

The Cosmetics Rules, 2020 marked a major restructuring of cosmetic regulation in India by replacing the earlier cosmetic-related provisions of the Drugs and Cosmetics Rules, 1945 and creating a dedicated framework for cosmetic import, manufacture, licensing, labelling, testing, inspection, and quality control. The Rules came into force on 15 December 2020 and introduced specific regulatory forms such as COS-1 for import registration applications, COS-5 for import registration certificates, COS-7 for GMP self-certification, and COS-8 for manufacturing licences. They also mandated compliance with Schedule M-II GMP requirements and applicable labelling provisions, including Legal Metrology requirements.

Further refinement occurred through the Cosmetics Amendment Rules, 2025, notified through G.S.R. 513(E) on 29 July 2025. These amendments clarified labelling terms such as “use before” and “date of expiry” and replaced “controlling officer” with “Controlling Authority” to improve consistency in regulatory terminology **[25,26]**. India is also considering broader reform through the proposed Drugs, Medical Devices and Cosmetics Act, 2025, which aims to replace the Drugs and Cosmetics Act, 1940 and strengthen central regulatory powers, digitize licensing, improve testing laboratory capacity, and enhance coordination between central and state authorities **[27, 28]**. In addition, the CDSCO SUGAM portal has become central to cosmetic import registration, with an August 2024 update limiting each online application to 50 products from 16 August 2024 to improve review efficiency while allowing multiple applications where required **[29, 30]**.

Table 1: Manufacturing and licensing requirements in India

Regulatory area	Key requirement	Responsible authority / form	Important details
Manufacturing premises	Compliance with Schedule M-II of the Cosmetics Rules, 2020	State Licensing Authority	Premises must have clean surroundings, adequate space, ventilation, lighting, drainage, sanitation, potable water supply, and proper waste disposal.
GMP compliance	Self-certification of Good Manufacturing Practices	Form COS-7	Applicant must submit GMP self-certification while applying for a manufacturing licence.
Manufacturing licence	Licence for cosmetic manufacture	Form COS-8 issued by State Licensing Authority	Licence remains valid in perpetuity, subject to payment of retention fee every five years [31]
Inspection	Verification of compliance after licence grant	State Licensing Authority	Manufacturing premises may be inspected to confirm compliance with Cosmetics Rules, 2020 and Schedule M-II.
Import registration	Mandatory registration before import	Central Licensing Authority / CDSCO	No cosmetic can be imported into India unless registered under the Cosmetics Rules, 2020.
Import application	Submission through SUGAM portal	Form COS-1	Application must include prescribed fee and supporting documents.
Import registration certificate	Approval for import of cosmetic products	Form COS-5	Issued by the Central Licensing Authority after evaluation; valid for three years unless suspended or cancelled.

Cosmetic Regulation in the United States

U.S. cosmetic regulation was historically based on the Federal Food, Drug, and Cosmetic Act of 1938, which prohibited adulterated and misbranded cosmetics but provided limited FDA authority compared with drugs and medical devices **[32,33]**. Before MoCRA, most cosmetics did not require pre-market approval, facility registration and product listing were voluntary, GMP requirements were non-mandatory, adverse-event reporting was not compulsory, and FDA generally relied on voluntary recalls **[34-36]**.The Modernization of Cosmetics Regulation Act of 2022 significantly expanded FDA oversight by introducing mandatory facility registration, product listing, safety substantiation, serious adverse-event reporting within 15 business days, FDA record access, mandatory recall authority, and future GMP regulations **[37-39]**. MoCRA also directed FDA to address fragrance allergen disclosure, asbestos testing in talc-containing cosmetics, and PFAS safety assessment, marking a major shift toward a more structured and surveillance-based regulatory framework **[40-42]**.

Ingredient safety and prohibited substances

Ingredient safety in India is mainly governed by the Cosmetics Rules, 2020 and BIS standards, especially IS 4707 Parts 1 and 2, which classify cosmetic ingredients into permitted colours, preservatives, UV filters, restricted substances, and prohibited substances. Hazardous ingredients such as

certain arsenic and lead compounds used for colouring, mercury compounds, hexachlorophene, and non-permitted colourants are restricted or prohibited, and manufacturers must ensure that raw materials comply with prescribed safety limits for heavy metals and other contaminants. In the United States, ingredient safety relies largely on manufacturer responsibility, except for colour additives, which generally require FDA approval. Although FDA does not routinely approve cosmetic ingredients before marketing, products must be safe, properly labelled, and not adulterated or misbranded. Specific substances are prohibited or restricted under 21 CFR Part 700, Subpart B, including bithionol, mercury compounds, vinyl chloride, certain halogenated salicylanilides, zirconium-containing aerosol cosmetics, chloroform, methylene chloride, chlorofluorocarbon propellants, and prohibited cattle material **[44–46]**.

Comparative analysis of labelling requirements in India Vs. U.S.A. [43]

	India	USA
1. Regulatory basis	Cosmetics Rules, 2020; Legal Metrology (Packaged Commodities) Rules, 2011; relevant BIS standards	Federal Food, Drug, and Cosmetic Act (FD&C Act); Fair Packaging and Labeling Act; FDA regulations including 21 CFR Part 701
2. Mandatory label information	• Manufacturer name and address • Batch number • Manufacturing licence number • Manufacturing date • Expiry or 'use before' date • Net quantity • Ingredient list • Directions for use, where applicable	• Product identity • Net quantity • Name and address of manufacturer, packer, or distributor • Ingredient list • Necessary warnings or directions for safe use
3. Additional requirements	• Imported cosmetics must mention country of origin and importer details • Warnings and cautions, where required • Hazardous or restricted ingredients must be declared, where applicable	• Labels generally in English (additional languages may also be used) • MoCRA requires a domestic address, telephone number, or electronic contact for adverse-event reporting to the Responsible Person
4. 2025 clarification	• **'Use before'** = use before the first day of the stated month • **'Date of expiry'** = expires on the last day of the stated month	4. Emerging requirement: Future FDA rulemaking on fragrance allergen disclosure may further expand labelling requirements
Key distinction	Greater emphasis on manufacturing/import traceability	Greater emphasis on post-market consumer contact and reporting

Figure 1: Comparative analysis of labelling requirement in India Vs. U.S.A

Comparative analysis of cosmetovigilance in India Vs. U.S.A.

Cosmetovigilance systems in India and the United States differ in maturity and enforceability. In India, cosmetovigilance is still emerging under the Cosmetics Rules, 2020, with manufacturers, importers, and marketers expected to monitor product safety and report adverse events or safety concerns to regulatory authorities. However, challenges remain, including limited awareness among small manufacturers, absence of a unified national adverse-event database, inconsistent state-level

implementation, and limited access to validated non-animal testing alternatives. Structured causality assessment methods, such as the AFSSAPS approach, may support better evaluation of cosmetic-related adverse reactions **[47]**. In contrast, MoCRA 2022 has made the U.S. system more formal by requiring the Responsible Person to report serious adverse events to the FDA within 15 business days, maintain adverse-event records, provide safety documentation when required, and comply with FDA recall actions for adulterated or misbranded cosmetics posing serious health risks. Thus, India is still strengthening its cosmetovigilance infrastructure, whereas the United States has moved toward a more enforceable post-market surveillance model.

RESULT AND DISCUSSION

This review shows that cosmetic regulation in India and the United States has undergone major modernization, although their regulatory approaches differ. India follows a licensing- and registration-based model for manufacture and import, strengthened by the Cosmetics Rules, 2020 and Cosmetics Amendment Rules, 2025, which provide clearer provisions for GMP, labelling, testing, prohibited cosmetics, and documentation. In contrast, the United States has historically relied on manufacturer responsibility and post-market surveillance, but MoCRA 2022 has expanded FDA oversight through mandatory facility registration, product listing, safety substantiation, serious adverse-event reporting, record access, and recall authority.

Both countries do not legally recognize "cosmeceuticals" as a separate category, and classification depends on intended use, composition, and claims. India relies strongly on BIS standards such as IS 4707 for ingredient safety and emphasizes licensing-linked labelling, while the United States places greater responsibility on manufacturers and now emphasizes traceability and adverse-event reporting under MoCRA. Overall, both jurisdictions are moving toward stronger safety substantiation, improved cosmetovigilance, transparent labelling, digital regulatory systems, non-animal testing approaches, and greater international harmonization.

CONCLUSION

This comparative review shows that cosmetic regulation in India and the United States is moving toward stronger safety oversight, transparency, and accountability. India's Cosmetics Rules, 2020 and subsequent amendments have established a structured licensing- and registration-based framework covering manufacture, import, labelling, GMP compliance, ingredient control, and enforcement. In contrast, the United States has shifted from a largely manufacturer-responsibility and post-market surveillance model to a more formal

regulatory system under MoCRA 2022, with mandatory facility registration, product listing, safety substantiation, serious adverse-event reporting, record access, and recall authority.

Both countries do not recognize "cosmeceuticals" as a separate legal category, and product classification depends on composition, intended use, and claims. While India emphasizes pre-market control, BIS standards, and manufacturing compliance, the United States focuses more on post-market accountability, Responsible Person obligations, and safety documentation. Despite these differences, both systems are converging toward improved ingredient safety, clearer labelling, GMP-based manufacturing, cosmetovigilance, and consumer protection. Overall, cosmetic regulation in both jurisdictions reflects a global shift toward science-based, lifecycle-oriented, and safety-focused regulation. Future harmonization may be supported by international cooperation, digital regulatory systems, non-animal testing methods, AI-based adverse-event monitoring, sustainability concerns, and greater alignment of GMP and ingredient safety standards.

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