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Comparative Analysis of Cosmetic Labelling Requirements in the United States and Japan

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Abstract

Cosmetic labelling regulations serve as a fundamental mechanism to ensure consumer safety, transparency, and regulatory compliance. With the expansion of international cosmetic trade, manufacturers must comply with varying regulatory frameworks across different jurisdictions. In the United States, cosmetics are regulated by the US Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. In Japan, cosmetic products are governed by the Pharmaceuticals and Medical Devices Law administered by the Ministry of Health, Labour and Welfare. This review presents a structured comparative evaluation of cosmetic labelling requirements in both countries, focusing on mandatory label elements, ingredient declaration systems, language obligations, claims regulation, warning statements, and enforcement mechanisms. The analysis identifies major similarities and regulatory differences that impact global market entry strategies.

Conclusion: Although both regulatory systems aim to protect consumer health, the United States follows a manufacturer-responsibility and post-market surveillance model, whereas Japan adopts a more prescriptive and language-specific regulatory structure. Understanding these distinctions is essential for regulatory compliance and successful international marketing.

Keywords: Cosmetics, Labelling, USFDA, MHLW, Regulatory Affairs, Comparative Review

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1. Introduction

Cosmetic products are widely used consumer goods intended for cleansing, beautifying, or enhancing appearance. Since these products are applied directly to the human body, regulatory authorities require accurate and transparent labelling to protect public health. Labelling ensures that consumers receive essential information regarding product identity, composition, usage instructions, and safety warnings.

Regulatory frameworks differ significantly across countries due to variations in legal systems and public health policies. The United States and Japan represent two major global cosmetic markets with established but distinct regulatory approaches.

In the United States, cosmetics are regulated under the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. **(1,2)** In Japan, cosmetics are governed by the Pharmaceuticals and Medical Devices Law (PMDL). **(3)** While both jurisdictions emphasize consumer protection, their labelling requirements vary in scope, language requirements, ingredient disclosure, and claims control.

This review provides a systematic comparison of cosmetic labelling requirements under both regulatory systems.

2. Regulatory Authorities and Legal Frameworks

2.1 United States Regulatory Framework

In the United States, cosmetic products are regulated by the US Food and Drug Administration (USFDA) under the authority of the Federal Food, Drug, and Cosmetic Act. **(1)** Cosmetics do not require pre-market approval, except for color additives. **(4,5)** However, manufacturers are legally responsible for ensuring product safety and preventing misbranding.

Cosmetic labelling requirements are specified under Title 21 Code of Federal Regulations (CFR), particularly Part 701. **(6)** The Fair Packaging and Labeling Act further ensures accurate disclosure of product identity and quantity. **(2)**

2.2 Japan Regulatory Framework

In Japan, cosmetics are regulated by the Ministry of Health, Labour and Welfare under the Pharmaceuticals and Medical Devices Law. **(3)** The PMDL categorizes

products as cosmetics, quasi-drugs, or pharmaceuticals depending on their intended use and claims.

Although cosmetics generally do not require pre-market approval, strict compliance with labelling standards and classification rules is mandatory. **(7,8)**

3. Definition and Classification of Cosmetics

3.1 Definition under USFDA

Under the Federal Food, Drug, and Cosmetic Act, cosmetics are defined as articles intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering appearance. **(1)** Products intended for therapeutic purposes are regulated as drugs.

3.2 Definition under MHLW

The PMDL defines cosmetics similarly but applies stricter categorization. Products with functional or physiological claims may be classified as quasi-drugs, resulting in additional regulatory controls. **(3,9)**

4. Regulatory Approval and Market Entry Pathway

4.1 United States Market Entry Pathway

Cosmetic products in the United States are under the control of the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act. Cosmetics are usually not pre-market approved as pharmaceuticals are before commercialization, other than individual regulated substances, like color additives. The main duties of manufacturers are to ensure that cosmetic products and their ingredients are safe to be used by consumers, and that the labeling of the products meets the relevant regulatory requirements.

In the prevailing regulatory system, any company planning to launch any cosmetic product into the American market should meet the safety standards and labeling requirements, before the product is marketed. The regulatory framework mainly depends on the accountability of manufactures and post-market regulation as opposed to pre-approval centralization. This practice enables manufacturers to sell cosmetic products without filing volumes of pre-market information with the regulatory agency, but the companies still are legally liable to product safety and other possible adverse effects of its products.

In order to facilitate regulatory oversight, the FDA has developed the Voluntary Cosmetic Registration Program (VCRP), which enables manufacturers, packers and distributors to voluntarily submit data about cosmetic products and manufacturing facilities. Doing the VCRP would allow the regulatory authority to receive data on cosmetic ingredients and products currently on the market in the United States, thus helping it conduct regulatory surveillance and safety evaluation. Registration under the VCRP is, however, not product approval and participation in the program is not obligatory.

In addition, cosmetic products sold in the United States are still under post-market regulatory measures. FDA can make visits to manufacturing plants, inspect product samples and take enforcement actions, including warning letters, product recalls or refusal to grant importation of goods when they are found contaminated, or misbranded. This is an important feature of the U.S. cosmetic regulatory system: such post-market regulation. **(10)**

4.2 Japan Market Entry Pathway

Cosmetic products in the United States are under the regulation of the United States Food and Drug Administration through the Federal Food, Drug and Cosmetic Act. The cosmetics in contrast to pharmaceuticals do not necessarily need pre-market approval before commercialization except certain regulated substances like color additives. The manufacturers are obligated at the main to provide safety to the cosmetic product and ingredients that they provide, and to ensure that the labeling of the product is as required by the regulation.

According to the existing regulation system, the companies entering the U.S. market with cosmetic products have to consider the safety standard and labeling requirements prior to the promotion of the product. The regulation system is based mostly on the responsibility of the manufacturers and post-market control but not on the centralized pre-approval. This would enable the manufacturers to promote cosmetic products without providing the regulatory authority with a lot of pre-market data but companies are still legally liable to the safety of their products and other possible side effects of their products.

FDA initiated the Voluntary Cosmetic Registration Program (VCRP) in order to facilitate regulatory compliance whereby manufacturers, packers and distributors can submit their information on cosmetic products and manufacturing facilities voluntarily. The VCRP will help the regulatory authority to receive information regarding cosmetic ingredients and products that are already marketed in the United States, thus helping in the regulatory surveillance and safety evaluation. Registration under the VCRP however does not amount to product approval and it is not obligatory to participate in the program.

Moreover, products of cosmetics sold in the United States continue to be the target of post-market regulation measures. In case it is discovered that adulteration or misbranding of products occurs, the FDA can perform inspections of manufacturing facilities, conduct a test of product samples, and implement enforcement actions, including warning letters, product recalls or import rejection. This type of post-market regulatory control is one of the main aspects of the U.S. cosmetic regulation system. **(11)**

Even though cosmetic products do not have to undergo a product approval prior to the marketing of a product, companies have to meet standards of ingredients and regulatory notifications, which must be followed within the framework of PMDL. Before distributing products, foreign manufacturers are required to file any notifications involving the importation and marketing of products to the regulatory bodies. Adherence to these regulatory needs will help in ensuring that cosmetic products sold in Japan are safe and of quality as set by the government. **(12)**

5. Mandatory Labelling Requirements

5.1 Language Requirements

In the United States, mandatory labelling information must be provided in English. **(6)** Additional languages may appear if English text is equally prominent.

In Japan, all required labelling information must be written in Japanese. **(8)** Non-Japanese labelling alone is considered non-compliant.

5.2 Product Identity and Net Quantity

US regulations require the statement of identity and net quantity of contents to appear on the principal display panel. **(4)** Net quantity must be expressed in US customary units and metric units where applicable. **(13)**

In Japan, product name and net content must be declared using metric units only. **(8)**

Table 1. Comparison of Core Labelling Requirements

Parameter	USFDA (United States)	MHLW (Japan)
Language	English	Japanese
Product Identity	Mandatory	Mandatory
Net Contents	US & Metric Units	Metric Only
Manufacturer Details	Name & Address	Marketing Authorization Holder
Country of Origin	Not Mandatory	Mandatory
Manufacturing Code	Optional	Mandatory

6. Ingredient Declaration Requirements

6.1 USFDA Requirements

Ingredients must be listed in descending order of predominance by weight. **(14)** Ingredients present at concentrations of 1% or less may be listed in any order after higher concentration ingredients. Color additives must comply with approved lists. **(5)**

6.2 MHLW Requirements

Japan requires full ingredient disclosure using standardized Japanese ingredient names published by the Japan Cosmetic Industry Association. **(15,16)** This requirement increases translation and compliance efforts for foreign manufacturers.

7. Claims and Advertising Control

USFDA prohibits false or misleading claims. **(17)** Products making therapeutic claims are reclassified as drugs.

Japan applies stricter claim screening. Claims implying physiological effects may result in quasi-drug classification under PMDL. **(9)**

8. Warning Statements

Certain US cosmetic products require specific warning statements, such as flammability warnings for aerosol products. **(18)**

In Japan, precautionary statements and usage instructions are required for designated cosmetic categories. **(8)**

Table 2. Extended Comparative Regulatory Differences

Parameter	USFDA	MHLW
Regulatory Authority	USFDA	MHLW
Legal Framework	FD&C Act, FPLA	PMDL
Pre-market Approval	Not required (except additives)	Not required
Stability Data	Not mandatory	Recommended documentation
Climatic Zone	Zone II (25°C ± 2°C / 60% RH ± 5%)	Zone I (25°C ± 2°C / 60% RH ± 5%)
PV Batches	Not required	Not mandatory
BA/BE Study	Not required	Not required
Language	English	Japanese Mandatory
Country of Origin	Optional	Mandatory
Dossier Format	eCTD (electronic Common Technical Document)	CTD/eCTD (PMDA-compliant; MAH-based submission system)
Claims Control	Post-market enforcement	Pre-classification strict control
Cost of Application	No registration fee	MAH licensing fee
Labelling Format	Flexible	Prescriptive
Challenges for Foreign Firms	Claims differentiation	Translation & nomenclature

Table 3. Comparison of Post-Market Regulatory Control

Parameter	United States	Japan
Regulatory Authority	FDA	MHLW
Post-Market Reporting	Voluntary (in most cases)	Mandatory MAH reporting
Recall System	FDA initiated or voluntary	Government coordinated

Market Surveillance	Inspection & complaints	PMDL monitoring

9. Compliance Challenges

Manufacturers targeting both markets face regulatory challenges including ingredient nomenclature conversion, translation accuracy, claims limitations, and packaging redesign. Regulatory planning is necessary to avoid misbranding and enforcement action. **(19)**

10. Future Perspectives

International harmonization efforts, including INCI nomenclature and global standards, may reduce regulatory disparities. However, national regulatory priorities and consumer protection standards are likely to maintain regional differences.

11. Conclusion

Both the USFDA and MHLW regulatory systems aim to ensure consumer protection through accurate cosmetic labelling. However, the United States emphasizes manufacturer responsibility and post-market oversight, while Japan follows a more structured and language-specific regulatory model. Awareness of these regulatory distinctions is critical for successful global cosmetic marketing.

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Conflict of Interest

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Reference

1. United States Congress. Federal Food, Drug, and Cosmetic Act. Washington (DC): US Government Publishing Office; 1938 Jun 25.
2. United States Congress. Fair Packaging and Labeling Act. Washington (DC): US Government Publishing Office; 1966 Nov 3.
3. Ministry of Health, Labour and Welfare. Pharmaceuticals and Medical Devices Law [Internet]. Tokyo: MHLW; 2014 Nov 25 [cited 2026 Feb 14]. Available from: https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/index.html
4. US Food and Drug Administration. Overview of cosmetics regulation in the United States [Internet]. Silver Spring (MD): USFDA; 2023 Jan 10 [cited 2026 Feb 14]. Available from: https://www.fda.gov/cosmetics/cosmetics-laws-regulations
5. US Food and Drug Administration. Color additive regulations for cosmetics. Silver Spring (MD): USFDA; 2023 Jan 15.
6. Code of Federal Regulations. Title 21 Part 701 – Cosmetic Labeling. Washington (DC): US Government Publishing Office; 2024 Jan 1.
7. Ministry of Health, Labour and Welfare. Standards for cosmetics under PMDL [Internet]. Tokyo: MHLW; 2023 Apr 1 [cited 2026 Feb 14]. Available from: https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/
8. Ministry of Health, Labour and Welfare. Cosmetic labeling standards in Japan [Internet]. Tokyo: MHLW; 2023 May 15 [cited 2026 Feb 14]. Available from: https://www.mhlw.go.jp/english/topics/cosmetics/
9. Ministry of Health, Labour and Welfare. Guidance on cosmetic and quasi-drug claims [Internet]. Tokyo: MHLW; 2023 Aug 1 [cited 2026 Feb 14]. Available from: https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/
10. US Food and Drug Administration. FDA authority over cosmetics: how cosmetics are regulated [Internet]. Silver Spring (MD): FDA; 2025 Mar 25 [cited 2026 Mar 25]. Available from: https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated
11. JpnPro Consultants. Cosmetics and quasi-drugs regulatory requirements in Japan [Internet]. Tokyo: JpnPro; 2022 Sep 10 [cited 2026 Mar 25]. Available from: https://www.jpnpro.com/en/services/cosmetics-regulations
12. Japan Cosmetic Industry Association. Regulatory compliance and manufacturing standards for cosmetics [Internet]. Tokyo: JCIA; 2023 Sep 5 [cited 2026 Mar 25]. Available from: https://www.jcia.org/en/regulations/
13. Ministry of Health, Labour and Welfare. Import and marketing authorization requirements for cosmetics [Internet]. Tokyo: MHLW; 2023 Jun 20 [cited 2026 Feb 14]. Available from: https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/import/
14. US Food and Drug Administration. Cosmetic ingredient labeling guide [Internet]. Silver Spring (MD): USFDA; 2023 Feb 5 [cited 2026 Feb 14]. Available from: https://www.fda.gov/cosmetics/labeling
15. Japan Cosmetic Industry Association. Japanese labeling names for cosmetic ingredients [Internet]. Tokyo: JCIA; 2023 Mar 10 [cited 2026 Feb 14]. Available from: https://www.jcia.org/en/standards/ingredient-names/
16. Japan Cosmetic Industry Association. Standards for cosmetic ingredient nomenclature [Internet]. Tokyo: JCIA; 2023 Mar 15 [cited 2026 Feb 14]. Available from: https://www.jcia.org/en/standards/
17. US Food and Drug Administration. Misbranding and false claims guidance [Internet]. Silver Spring (MD): USFDA; 2023 Jul 12 [cited 2026 Feb 14]. Available from: https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement
18. US Food and Drug Administration. Warning statements for cosmetic products [Internet]. Silver Spring (MD): USFDA; 2023 Oct 2 [cited 2026 Feb 14]. Available from: https://www.fda.gov/cosmetics/labeling
19. US Food and Drug Administration. Cosmetic compliance and enforcement activities [Internet]. Silver Spring (MD): USFDA; 2023 Dec 1 [cited 2026 Feb 14]. Available from: https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement