Review Article

USA Cosmetic Regulations Updates - Scenario from 1938 to 2022

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ABSTRACT

Since ancient rites to modern beauty practices, cosmetics have played a significant role in human culture and personal grooming for generations. Despite their widespread benefits and appeal, many cosmetics contain potentially harmful ingredients that pose risks to consumer health. The United States has established a strict regulatory system to guarantee the safety of cosmetic items in response to these concerns. The Food, Drug, and Cosmetic Act (FDCA), Fair Packaging and Labeling Act (FPLA), and the Modernization of Cosmetics Regulation Act (MoCRA), together set down extensive regulations for the marketing, labeling, and safety of cosmetics. By enforcing strict guidelines for ingredient disclosure, product testing, and consumer protection, these regulations reduce health hazards and improve the general safety of cosmetics available in the interstate commerce. This regulatory oversight provides consumers with greater confidence in the safety and efficacy of the cosmetic products they use.

Keywords: Cosmetics, USA Regulations, Food, Drug, and Cosmetic Act (FDCA), Fair Packaging and Labeling Act (FPLA), Modernization of Cosmetics Regulation Act (MoCRA), Cosmetic Registration.

INTRODUCTION

HISTORY OF COSMETICS

Cosmetics are used from ancient times across different parts of the world including Egypt, China, Japan, England and India. Cosmetics became an integral part of health and hygiene. Simple ingredients from the kitchen like rice and gram flour, oils like lavender, chamomile, rose, peppermint, olive and aloe are used in the preparation of cosmetics. During 1300- in Elizabethan England, dyed red hair came into fashion. Later in the early 20th century, Zinc oxide was widely used as a facial powder which were mainly used by actors. As the time passed by Edwardian Society, pressure on women increased to look youthful and young, as a result the use of cosmetics has been increased drastically including many excipients.[1]

In 1906, The Pure Food and Drug Act of 1906 did not apply to cosmetics since they were seen to be non-serious health concerns. The Federal Food Drug and Cosmetic (FD&C) Act, 1938 was later passed by Congress as a result of an eyeliner-related event, greatly enhancing the FDA's authority over cosmetics. [(1)] In 1966, The Fair Packaging and Labeling Act (FPLA) is passed by Congress and mandates that all consumer goods sold in the market have truthful and educational labels. The FDA is responsible for implementing the regulations on foods, medications, cosmetics, and medical devices.

REGULATION OF COSMETICS IN USA

The Federal Food, Drug, and Cosmetic Act (FD&C Act), Fair Packaging and Labeling Act (FPLA) and Modernization of Cosmetics Regulation Act, 2022 (MoCRA) are the three most primary statutes that deal with cosmetics that are marketed in the United States. These laws provide the FDA the power to regulate cosmetics. Considering the exception of color additives, these rules exempt cosmetic items and substances from FDA pre-market review. It is, however, forbidden to market cosmetics that have been tampered with or mislabeled.

Laws that FDA Enforces for Cosmetics are The Federal Food, Drug, and Cosmetic Act (FD&C Act), Fair Packaging and Labeling Act (FPLA) and Modernization of Cosmetics Regulation Act, 2022 (MoCRA).

Title 21 of the Code of Federal Regulations (21 CFR) Part 700 Chapter 1, Subchapter G, and Part 701 contains regulations pertaining to labeling and cosmetics [(2)]; and FPLA, 15 CFR; Chapter 39 addresses the commerce and trade of cosmetics.[3]

COSMETICS: The FD&C Act defines cosmetics by their intended use, as **"articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance**" (FD&C Act, sec. 201(i)). Examples include skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, and deodorants (excluding soap). [(4)]

What Constitutes Adulterated Cosmetics
The FD&C Act's Section 601 [21 U.S.C. 361] outlines the following criteria that make a cosmetic regarded adulterated:
When a cosmetic is deemed contaminated, it is because...

a. If it has any toxic or deleterious materials on it that might be harmful to people if used as recommended by the label or under normal or customary usage circumstances. However, this clause will not apply to coal-tar hair dye, as its label prominently states the warning, "Caution: This product contains ingredients that may cause skin irritation on certain individuals.

A patch test should be made in accordance with the accompanying directions."

b. If it contains any amount of unclean, rotten, or degraded material, either entirely or in part.

c. If it was made, packaged, or stored in an unhygienic manner, where it might have gotten contaminated with dirt or became harmful to one's health.

d. If the container is made whole or in part of any toxic or harmful material that could endanger the health of the contents.[5]

What Constitutes Misbranded Cosmetics

- Inaccurate or deceptive information;
- Absence of necessary information,
- Readability and conspicuousness of necessary information,
- Misleading packaging,
- Improper packaging and labeling of color additives, and
- Deficiencies where the Poison Prevention Packaging Act requires special packaging.[5]

FEDERAL FOOD, DRUG, AND COSMETIC ACT

The Code of Federal provisions (21 CFR) have various provisions relating to cosmetics, including:

21 CFR Part 700 Chapter 1, Subchapter G, discuss about the regulation of cosmetics in USA. Table 1 describes the subparts of 21CFR part 700 in concern with cosmetics.

Table 1: Summary of Federal Food Drug and Cosmetic Act provisions related to cosmetics

FEDERAL FOOD DRUG AND COSMETIC ACT	
CFR PART	**REGULATION**
21 CFR Part 700 Chapter 1, Subchapter G	
Subpart A:	**General Provisions**
Subpart B	**Requirements for Specific Cosmetic Products**
21 CFR Part 701,	
Subpart A:	**General provisions for cosmetic labelling**
➢ § 701.1 Misbranding. ➢ § 701.2 Form of stating labelling requirements. ➢ § 701.3 Designation of ingredients. ➢ § 701.9 Exemptions from labelling requirements[6]	
Subpart B	**Package Form 701.10 – 701.13**
➢ § 701.10 Principal display panel ➢ § 701.11 Identity labelling ➢ § 701.12 Name and place of business of manufacturer, packer, or distributor ➢ § 701.13 Declaration of net quantity of contents[7]	
Subpart C:	**Labelling of Specific Ingredients**
➢ § 701.20. Detergent substances, other than soap, intended for use in cleansing the body ➢ § 701.30. Ingredient names established for cosmetic ingredient labelling.[8]	
21 CFR Part 710	
Voluntary Registration of Cosmetic Product Establishments[9]	

According to 21 CFR Part 700 Chapter 1, Subchapter G, Subpart B: Requirements for Specific Cosmetic Products the cosmetics containing following ingredients are considered as adulterated:

1. Bithionol
2. Mercury compounds
3. Vinyl chloride
4. Halogenated salicylanilides
5. Aerosol cosmetics containing zirconium
6. Chloroform
7. Methylene chloride
8. Chlorofluorocarbon
9. Prohibited cattle materials
10. Sunscreen ingredients.[7, 11]

According to 21 CFR Part 701, Subpart A discusses about the General provisions for labeling of cosmetic.

A cosmetic is said to be "misbranded" if its labeling is inaccurate or deceptive, particularly when contrasted with other cosmetics, food, drugs, or devices. Unless the product is supplied in an area where another language is widely spoken, such as Puerto Rico, all required information on cosmetic labels must be written in English. Every component in a cosmetic product must be listed on the label in the order that they are present, from most to least. Exemption from this label are flavors and fragrances are simply denoted by "fragrance" or "flavor." The label may include "and other ingredients" rather than specifying an ingredient if it is proprietary. When a product's formula changes and both the old and new versions are marketed simultaneously, the label has to make it obvious that the formula has changed or mention both sets of components. Cosmetics that are transported to a different location for processing, labeling, or repackaging are momentarily free from labeling regulations during transportation or at the processing facility. If the shipping and processing facilities are owned by the same business, or if a formal agreement guarantees that the product won't be tampered with or mislabeled after processing, then this exemption is applicable.[6]

21 CFR Part 701, Subpart B: Package Form 701.10 – 701.13

The portion of the cosmetic label that shoppers are most likely to view in a store is the principal display panel.

it can be quantified for different shapes of cosmetics by following methods

- **Rectangular Package**: Determine the front side's height and breadth.
- **Cylindrical Package**: Calculate the circumference by 40% of the height.
- **Other Shapes:** Unless there is an evident top or front, in which case the entire top or front is regarded as the display panel, measure 40% of the overall surface area.

The nature of the cosmetic must be stated on the label. One way to accomplish this is:

1. By using the common or standard name.
2. Choosing a creative or descriptive name that the general audience may comprehend.
3. Including an image that illustrates the purpose of the product.

The maker, packer, or distributor's name and address must be on the label, including details like street address, city zip code, state, and the label must accurately state how much of the product is in the package, using weight, measure, or count abbreviations.[7]

21 CFR Part 701 Subpart C: Labeling of Specific Ingredients

The FDA states that a product qualifies as "soap" if the majority of its non-water component is composed of fatty acid alkali salts, which provide the product its cleaning properties and the product is sold, advertised, and branded as "soap. "If a cleaning product doesn't fit these requirements, it may be subject to different regulations and isn't legally classified as "soap".[8] Some chemical ingredients have specific names that must be used on cosmetic labels.[8] For example Trichlorofluoromethane to be represented as Chlorofluorocarbon 11, Dichlorodifluoromethane as Chlorofluorocarbon 12 (based on nomenclature for chlorofluorocarbons used as propellents).

21 CFR Part 710: Voluntary Registration of Cosmetic Product Establishments [9]

Within 30 days of the operation starting, any maker of cosmetics can voluntarily register themselves under the voluntary registration of companies selling cosmetic products. In order to register, they must complete out Form FD-2511, (Registration of Cosmetic Product Establishment,) with the necessary product-related data, and send it to the FDA. Every registered cosmetic enterprise will be given a permanent registration number. The form that is submitted will be examined by the FDA

Beauty salons, cosmetologists, retailers, pharmacies, and other individuals or businesses who administer, dispense, or distribute cosmetic products at retail from a single location and who do not produce or package cosmetic products there. Individuals who make, produce, compound, or process cosmetic items only for use in research, training, pilot plant production, or chemical analysis and who do not sell these products; physicians; hospitals; clinics; and public health organizations are exempted from this voluntary registration.[9]

FAIR PACKAGING AND LABELING ACT

The Fair Packaging and Labeling Act (FPLA or Act), enacted in 1967, summarized in Table- 2, mandates that all "consumer commodities" be labeled with information on the product's identity, net contents, and producer, packer, or distributor's name and address. This directive is sent to the Federal Trade Commission and the Food and Drug.[10]

Table 2: Summary of Fair Packaging and Labeling Act Provisions Related to Cosmetics [10]

Title 15- Commerce and Trade, Chapter 39- Fair Packaging and Labeling Program	
§1451	Congressional Delegation of Policy
§1452	Unfair and Deceptive Packaging and Labeling: Scope of Prohibition
§1453	Requirements of Labeling; Placement, Form, and Contents of Statement of Quantity; Supplemental Statement of Quantity
§1454	Rules and Regulations
§1455	Procedures for Promulgation of Regulations
§1456	Enforcement
§1457	Annual Reports to Congress: Submission Dates
§1458	Cooperation with State Authorities; Transmittal of Regulations to States; Non-interference with Existing Programs
§1459	Definitions
§1460	Savings Provisions
§1461	Effect Upon State Law
§1451	note Effective Date

Purpose of the Act: The FPLA is designed to facilitate value comparisons and to prevent unfair or deceptive packaging and labeling of many household "consumer commodities." Labels and packaging should accurately indicate the quantity of contents and make it easier for consumers to compare product prices. Product packaging and labeling that deviate from the guidelines in this chapter is prohibited. Unless they are the ones packing or labeling, or unless they specify how it is done, these regulations do not apply to wholesale or retail distributors. The product's identification as well as the name, address, and maker, packer, or distributor must be displayed on the label. The net quantity of contents must be stated on the label in the standard inch/pound format with the relevant units. Any additional statements about quantity shouldn't use terms that exaggerate the amount of product in the package. The Secretary or the Commission promulgate rules

regarding FPLA. In case the industry fails to abide by these rules then they may be subjected to hearings, judicial review and enforcement.[10]

LABELLING REQUIREMENTS

Cosmetics labels have to be accurate and not deceptive. The label should include the following information:

- A precise description of net content;
- A name and address for the firm;
- An identification statement outlining the characteristics and applications of the product.
- Distributor statement: xxxx produced the product or xxxx distributed it.
- Material information. One type of deceptive labeling that results in a product being misbranded is the omission of important information.
- Caution and warning signs.
- Ingredients used.[10]

On labels of the product in the United States, ingredients must be named by their "common or usual names" in English, in descending order of predominance. There are instances where INCI names deviate from these popular names. Latin names are commonly used in INCI names for plant components. Considering that using common or ordinary names is mandated by US legislation. Parenthetically inserted Latin words might come after an ingredient's common or typical name. Aloe (*Aloe barbadensis*) extract, for instance.[10]

MODERNIZATION OF COSMETIC REGULATION ACT 2022 (MOCRA)

President Biden signed the Modernization of Cosmetics Regulation Act (MoCRA) 2022 into law on December 29, 2022. MoCRA is the first significant amendment to FD&C act since 1938. It marks the first update to federal cosmetic regulations in more than 80 years. It was introduced to strengthen the regulation of cosmetics in the United States. Numerous provisions in this regulation support the health and safety of salon employees as well as the safety of cosmetic items. To guarantee public trust in cosmetic safety, some standards have to have been reinforced further. States must act immediately to impose regulations on the use of hazardous substances in cosmetics.[11] Table 3 gives the comparison of regulatory aspects on cosmetics before and after MoCRA.

Table 3: Comparison of different cosmetic aspects before and after MoCRA [12]

S.NO	Aspect	Prior to MoCRA 2022	After MoCRA 2022
1.	**Registration**	Registration for cosmetic facilities is voluntary.	Registration for cosmetic facilities is mandatory.
2.	**Good manufacturing practices (GMP)**	No specific GMP required for cosmetics	Establishing and enforcing of good manufacturing practices (GMP) for cosmetics
3.	**Recall authority**	FDA can take enforcement action on cosmetics products shown to be adulterated and/or misbranded	Mandatory recall of adulterated/misbranded cosmetic products.
4.	**Fragrance Ingredients Disclosure**	Not required	Mandatory disclosure of certain fragrance allergens on the label of cosmetics.
5.	**Adverse Event reporting**	Voluntary reporting of serious adverse events.	Mandatory reporting of serious adverse events within 15 business days.
6.	**Product Listing**	No requirement to list cosmetic products	Mandatory listing of cosmetic products with the FDA
7.	**Record Keeping**	No mandate from the law to keep safety records	Manufactures must maintain safety records for their products and provide them upon FDA request/inspection.
8.	**Labelling Requirements**	Basic labelling requirements	Enhanced labelling requirements, including contact information of responsible person for adverse events and fragrance allergens.
9.	**Safety substantiation**	No formal requirements for safety substantiation	Manufacturers must ensure products are safe, and have adequate substantiation for safety claims.
10.	**Small Business Exemptions**	No specific exemptions for small businesses	Certain exemptions for small businesses regarding some reporting and compliance requirements.

Salient Features of MoCRA:

1. **Record inspection and accesses:**

   The cosmetic manufacturing companies are required to maintain records regarding to safety records, product labelling and manufacturing processes which may be requested by the FDA for inspection.

2. **Safety Substantiation:**

   Cosmetic manufacturers are responsible to guarantee the safety of their goods and provide sufficient safety evidence. Additionally, these firms must keep documents attesting to the sufficiency of the safety evidence.

3. **Mandatory serious adverse event reporting:**

   Reporting of major adverse events involving cosmetic items must be done mandatory within 15 working days of a responsible person reporting the incident. Adverse event reports must be kept on file by the companies, and the FDA may review them in the course of an inspection.

4. **Facility registration:**

   Cosmetic manufacturers and processors should mandatorily register their facilities with FDA. And registration must be renewed for every 2 years.

5. **Product Listing:**

   The cosmetic manufactures must list each marketed product, including product ingredients with FDA. Any updates provide annually.

6. **Mandatory recall authority:**

   The companies should Mandatory recall the cosmetic products if they are found to be misbranded, adulterated or unsafe.

7. **Labelling requirements:**

   The companies must include contact information on cosmetic product labels for consumers to report adverse events. Disclosure of certain fragrance allergens on the cosmetic product labels.

8. **Good Manufacturing Practice (GMP) Rule:**

   The FDA is tasked with establishing regulations on Good Manufacturing Practices (GMP) for cosmetic products. The companies should maintain the records, during inspections to evaluate compliance with GMPs.

9. **Testing Methods for Detecting Asbestos in Talc-containing cosmetics Rule:**

   To provide uniform testing procedures for identifying asbestos in cosmetic items containing talc, the FDA created standards.

10. **Report on PFAS in cosmetics:**

    The safe use of per-and polyfluoroalkyl substances ("PFAS") in cosmetic products need to be reported.

Exemptions of small business:

Small businesses with annual sales below $1M are exempt from certain requirements, such as GMP regulations and product listing requirements.[13]

Cosmetic Registration process in the USA:

The FDA's clearance is not required for cosmetic items or chemicals (except from colour additives) before they may be sold. It is the company's duty to guarantee that the ingredients and cosmetic goods it sells are safe, correctly labelled, and compliant with all legal requirements. The voluntary registration of cosmetics under the Voluntary Cosmetic Registration Program (VCRP) is strongly encouraged by the FDA. Only cosmetics that are sold to American consumers are covered under the VCRP. Cosmetics intended exclusively for professional usage, such as those found in spas, skin care centre's, and beauty salons, are not covered by this. The figure 1 discusses about the steps required for cosmetic registration process in the USA.

Figure 1: Voluntary Cosmetic Registration Program (VCRP) cosmetic Registration process

Step 1: Check the list of ingredients

The following ingredients are prohibited in cosmetics in the United States:

Halogenate Salicyl anilides, Mercury compounds, Chlorofluorocarbon Propellants, Methylene chloride, Hexachlorophene (Nabac), Bithionol, Prohibited Cattle Material, Vinyl chloride, Zirconium- containing complexes.

Step 2: Check content of labelling & packaging

Labelling requirements

The Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and labels Act (FPLA) provide the FDA the ability to regulate cosmetic labels. According to the statute, the FDA lacks the resources and power necessary to approve cosmetic product labels before they go on sale. Proper labelling of items is the duty of the maker and/or distributor. A product with an incorrect brand might arise from labelling rules not being followed. The language used on labels must be English.

Packaging requirements

When sold at retail, the FDA mandates that all liquid mouthwashes and cosmetic vaginal products be packed in tamper-resistant packaging. If a package contains a barrier to entrance, such as a shrink or tape seal, that, if broken or absent, notifies the customer that tampering has taken place, it is said to be tamper resistant.

Step 3: Register Establishment with FDA:

The FDA must first be contacted to initiate a new account request before an institution may be registered. Owners or operators of facilities that manufacture or package cosmetics can fill out FDA Form 2511 and upload it to the VCRP platform after creating an account. It is noteworthy that distributors are not permitted to register an institution.

To complete Form 2511 the following information is required:

- Parent Company name
- Address
- Owner or Manager of the Establishment
- Other businesses Trade names
- Establishment Authorized individual

Step 4: File cosmetic product ingredient statement

Form 2511 can be used to continue filing the ingredients for a cosmetic product after it has been finished and filed. Form 2512, the Cosmetic Ingredient Statement, must be completed in order to submit a cosmetic formulation to the FDA (CPIS).

To complete Form 2512 the following information is required:

- Labeller information
- Manufacturer Information
- Packer information
- Indicate whether filed product is already distributed in the USA
- Product information
  - Select product category
  - Product code
  - Brand name/ specific product name
  - Product website
  - Upload label images

• Ingredient Information

  - Can enter either CAS/ VCRP code number or common, usual, chemical name.

• Authorized individual name[14]

Because of its plans to create a program for submitting the facility registrations and product listings required by the "Modernization of Cosmetics Regulation Act of 2022," the U.S. Food and Drug Administration (FDA) has ceased accepting submissions to the Voluntary Cosmetic Registration Program (VCRP) as of March 27, 2023. (MoCRA)

Because MoCRA requires certain companies to register their facilities and list their products with FDA, FDA is creating a new system to handle the large number of submissions that will result. As a result, FDA will no longer process or accept submissions to the voluntary registration program (VCRP) or use the voluntary registration system.[15]

NEW SYSTEM

For Industry-Decision Tool

The FDA has created a tool to assist in determining if registering a facility that produces cosmetics is necessary. Visit Decision Tool and provide answers to a series of questions to utilize the tool.

Below are options for registration and listing submissions.

(i) Electronic Submissions:

Cosmetics Direct

Cosmetics Direct is a user-friendly data entry tool offered by the FDA for the creation and saving of Structured Product Labeling (SPL) submissions for cosmetic product facilities and listings. The tool eliminates the need for the Electronic Submissions Gateway (ESG) by performing preliminary validations, creating and saving SPL submissions, and submitting them to the FDA for internal processing.

Electronic Submissions Gateway (ESG)

Alternatively, the FDA's Electronic Submissions Gateway (ESG) or any Structured Product Labeling (SPL) authoring program, such as SPL Xforms, may be used to submit cosmetic product facility registrations and cosmetic product listings online. Before providing data, users of the FDA ESG system must apply for a free account, a process that might take one to three weeks. For this reason, the FDA strongly advises registrants to apply for ESG accounts well in advance of the legally-mandated deadline for submitting data.

SPL X forms

One method for generating an SPL file including facility registration and listing details for cosmetic products is to use X forms.

New Features

The FDA declared on July 29, 2024, that the following new functionalities for cosmetic product listing in Cosmetics Direct will be available: The ability to remove cosmetic items that were previously listed in Cosmetics Direct but are no longer available on the market is granted to responsible individuals via the cessation of cosmetic product listing function.

- The relisting feature provides responsible persons the option to relist cosmetic products that were previously discontinued in Cosmetics Direct and are being brought back to the market.

Paper Submissions

To improve the agency's efficiency and timeliness in data submission and management, FDA highly promotes electronic submissions. The following paper forms are available:

- FDA 5066 Form: Cosmetic Product Facility Registration.
- FDA 5067 Form: Listing of Cosmetic Products.[16]

CONCLUSION

In conclusion, the Modernization of Cosmetic Regulation Act (MoCRA), which was introduced in 2022 and represents the first significant revision to the FDA's monitoring of cosmetics since 1938, has greatly changed the way the agency oversees cosmetics. With the implementation of MoCRA, compliance is now required; cosmetic facilities must register, products must be listed, good manufacturing standards must be followed, and adverse event reporting must occur. With relation to the disclosure of fragrance ingredients in particular, this attempts to improve consumer safety and transparency. Furthermore, the Fair Packaging and Labeling Act supports these initiatives by guaranteeing that cosmetic items be accurately and clearly labeled, giving consumers access to pertinent information. MoCRA reinforces the foundation created by the Fair Packaging and Labeling Act by imposing a required system in place of the voluntary program for cosmetic registration, guaranteeing that cosmetics on the market are safe and live up to consumer expectations. Although there is always potential for improvement, MoCRA establishes a strong basis for enhancing the safety of cosmetic products and safeguarding the public's health.

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