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A Paradigm Shift in U.S. FDA Cosmetic Regulations: Modernization of Cosmetics Regulation Act (MoCRA)

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ABSTRACT:

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) signifies the most significant reform in U.S. cosmetic regulation since 1938. Previously governed under the Federal Food, Drug, and Cosmetic Act (FD&C Act), cosmetic oversight in the U.S. largely relied on voluntary measures. MoCRA establishes a mandatory, structured, and enforceable regulatory framework. This article reviews the key features of MoCRA and compares them to the former voluntary registration system, highlighting implications for domestic and international cosmetic manufacturers.

Introduction

For many years, the industry of cosmetics in the United States of America has been driven under minimal supervision. The U.S. Food and Drug Administration (FDA) had some degree of authority to put in force any pre-market regulations for cosmetics. The enforcement of MoCRA in December 2022 marks a revolutionary step towards inclusive regulatory compliance. As the importance of consumer safety and global harmonization grows, the shift from a voluntary to a mandatory regulatory framework becomes very important for the stakeholders.

Cosmetic regulations were regulated by the Federal Food, Drug, and Cosmetic (FD&C) Act since the year 1938. MoCRA is now the most significant expansion of the FDA regulations, ensuring the safety of cosmetic products used daily by many consumers.

The Former Voluntary Cosmetic Registration Program (VCRP)

The formal regulations for cosmetics were governed under the Voluntary Cosmetic Registration Program (VCRP) (1). It included two components:

(i) Facility registration (Form FDA 2511)

Under this form, FDA 2511, cosmetic product manufacturers, packers, importers, or distributors in the U.S. underwent the voluntary registration of their establishments with the FDA.

This form helped the FDA to:

- Recognize facilities involved in cosmetic production.
- Record the domestic and foreign companies marketing cosmetics in the U.S.
- Permit quicker communication in case of product safety concerns or ingredient alerts (2).

(ii) Cosmetic product ingredient statement (Form FDA 2512)

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The Form FDA2512 was a form for packers, manufacturers, or wholesalers of cosmetic products in the US to voluntarily file the ingredient information with the U.S. FDA (3).

Key features of the VCRP included:

- Completely voluntary registrations
- Limited participation from the industry
- No enforcement authority
- Good Manufacturing Practices were not obligatory
- Adverse event reporting was not mandatory

The VCRP operated more as a database for FDA visibility than as a regulatory tool (1).

MoCRA: A Regulatory Revamp

The Modernisation of Cosmetics Regulation Act (MoCRA), as part of the 2023 omnibus bill (H.R.2617), was enacted on December 29, 2022. It was added as section 607 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (4).

The MoCRA implemented the below mandatory requirements for cosmetic manufacturers and processors:

(i) Facility Registration
The Manufacturers and processors are now obliged to register their facilities with the FDA and will have to undergo the process of renewing their registration every two years.

FDA has, under MoCRA taken up the responsibility to put on ice a cosmetic facility's registration if the agency deems so because a product has a likelihood of leading to a serious adverse health aftermaths or death, because of a failure that cannot be correlated to a product or products that are manufactured by the said manufacturer.

Upon suspension of the facility registration by the USFDA, the manufacturer will be prohibited from distributing, selling, or otherwise introducing into the USA market (5).

(ii) Product Listing
Each marketed cosmetic product must be listed with the FDA, including the details of the labeling and ingredient disclosures.

Multiple cosmetic products with similar formulations differing only in terms of colours, flavours, fragrances, or ingredient amounts can be submitted under a single listing.

The USFDA does not make publicly available the product listing number given to a cosmetic manufacturer (5).

(iii) Adverse Event Reporting
A company or a responsible person is mandated to inform any serious adverse events linked to a cosmetic product within 15 business days to the FDA, along with a duplicate of the label of said cosmetic product.

The adverse event reporting is to be done using the form FDA 3500A-Mandatory Reporting, which is available on the MedWatch website of the USFDA (4).

(iv) Safety Substantiation
Cosmetic companies must provide evidence that their products are safe for the intended use.

This can be proven using various tests, studies, or scientific literature. All probable exposures to a cosmetic product, including frequency and duration of use, can be taken into consideration.

It is mandatory to completely record and maintain an accountable and traceable safety evaluation for FDA review (6).

(v) Good Manufacturing Practices
The FDA has made a draft Cosmetic Good Manufacturing (GMP) Guidelines incorporating the aspects of ISO 22716:2007 (International Organization for Standardization standard for cosmetic GMPs).

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The FDA is currently accepting comments on this draft guidance on the Cosmetic GMP from manufacturers and other stakeholders (7).

(vi) Labelling Requirements

Any cosmetic product containing fragrance allergens or products to be used by professionals only shall be declared or indicated on the label.

Products being imported into the US market must have a domestic contact's information mentioned on the label.

Registration Process under MoCRA

The USFDA has introduced a new Structured Product Labelling (SPL) authoring tool called COSMETICS DIRECT. It is an online tool through which facility registration and product listing of cosmetics can be undertaken without having to exploit the Electronic Submissions Gateway (ESG) (8).

Although the ESG still stands as an alternative submission gateway apart from the COSMETICS DIRECT, the FDA has also developed paper forms 5066 and 5067 as a substitute for electronic submission (9)(10).

Exemptions

Under MoCRA, certain exemptions have been granted for Facility registration. It includes facilities such as (5):

1. Beautifying shops or salons
2. Retailers or direct sellers of cosmetics
3. Hospitals or clinics
4. Hotels or airlines giving complimentary cosmetic products
5. Trading shows
6. Testing or research facilities
7. Re-labellers and re-packers

Table No. 1: MoCRA vs. VCRP

	VCRP	MoCRA
Facility Registration	Voluntary	Mandatory
Product Ingredient Listing	Voluntary	Mandatory
Forms	2511 and 2512	5066 and 5067
Adverse Event Reporting	Not required	Mandatory (serious AEs)
Safety Verification	Not imposed	Mandatory
GMP Compliance	Not mandatory	Enforceable
Labelling	Basic	Enhanced (e.g., allergens, contacts)
Act enforcement	Limited	Broad enforcement powers, including inspections and recalls

Implications for the Industry

For Companies in the USA:

(i) Compliance of the infrastructure as per the new GMP guidelines.
(ii) Greater accountability and documentation
(iii) Increased risk of penalties for non-compliance

For International Companies:

(i) Appointing an agent residing in the USA has been made mandatory for international companies having their cosmetic market in the USA.
(ii) All the manufacturing facilities must register for marketing in the USA.
(iii) The facilities must adhere to the new labelling and safety requirements.

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Challenges

The regulatory burden on small and medium enterprises will increase as they will have to be in line with many upgradations in their facility as per GMP, increase record keeping, prove the safety of their products, and much more.

There is no clear transition timeline available for GMP implementation as the guideline has not yet been approved and published.

There is great potential for duplication with EU/ASEAN requirements (11).

Opportunities

MoCRA has brought in a very safe future for the citizens of the USA. With its implementation, the consumer trust and brand credibility of any cosmetic product being sold in the USA market will increase.

With the increased requirement for post-marketing surveillance, any adverse event that occurs shall be resolved in a faster way.

The possibility of global regulatory convergence could be achieved.

Conclusion

MoCRA has modernised the US cosmetic regulatory framework by transforming a passive, voluntary system into a proactive, mandatory one.

It brings the U.S. closer to international cosmetic regulatory standards while providing increased consumer safety.

Manufacturers must quickly adjust and adapt to the new compliance responsibilities to maintain market access in the United States and benefit from the trust that comes with FDA-aligned transparency.

Conflict of interest

The authors declare that there is no conflict of interest.

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