Personal Care Products Council
Committed to Safety, Quality & Innovation

Checklists on Modernization of Cosmetics Regulation Act (MoCRA) Registration and Listing Requirements

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The Personal Care Products Council
1620 L Street, N.W., Suite 1200
Washington, D.C. 20036
Phone: 202/331-1770
Fax: 202/331-1969
www.personalcarecouncil.org

TABLE OF CONTENTS

I. INTRODUCTION

A. Background

On December 30th, 2022, the Modernization of Cosmetic Regulation Act (MoCRA) of 2022 was signed into law. It includes new regulatory requirements for cosmetics manufactured, processed, distributed, or marketed in the United States, including the registration of cosmetic product manufacturing or processing facilities and listing of cosmetic products with the U.S. Food and Drug Administration (FDA). In many cases, these registration and listing activities may need to be coordinated between brand owners, third party manufacturers, and other third parties.

PCPC has developed the checklists in this document to help facilitate communications between companies who seek to coordinate their cosmetic registration and listing activities. Companies using this resource are encouraged to modify any or all parts based on their unique business needs. Ultimately, it is the responsibility of companies to comply with the Federal Food, Drug, and Cosmetics Act (FDCA) and FDA's implementing regulations; by providing this document as a reference, PCPC does not take responsibility for companies' legal and regulatory obligations. This document does not constitute legal advice and is not intended to confer any legal opinions or guidance.

PCPC originally published this document in September 2023. FDA is expected to begin accepting cosmetic registration and listing submissions in October 2023. It is not yet known when FDA may finalize its relevant guidance document or provide other information about compliance with cosmetic registration and listing requirements. PCPC may update this document to incorporate new information from FDA and for the purpose of improving this resource over time.

B. Definitions

Term	Definition
Contract Manufacturer	Means a facility that engages in one or more steps in manufacturing or processing a cosmetic product on behalf of another company.
Cosmetic Product	As defined in section 604(2) of the FDCA, means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.
DUNS Number	The Data Universal Numbering System (DUNS) number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). The DUNS Number is site-specific. Therefore, each distinct physical location of an entity (such as branches, divisions, and headquarters) may be assigned a DUNS number.
Facility	As defined in section 604(3) of the FDCA, includes any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States. This term does not include any of the following: (i) Beauty shops and salons, unless such establishment manufactures or processes cosmetic products at that location. (ii) Cosmetic product retailers, including individual sales representatives, direct sellers (as defined in section 3508(b)(2) of the Internal Revenue Code of 1986) retail distribution facilities, and pharmacies,

Term	Definition
	unless such establishment manufactures or processes cosmetic products that are not sold directly to consumers at that location., (iii) Hospitals, physician's offices, and health care clinics. (iv) Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer. (v) Entities (such as hotels and airlines) that provide complimentary cosmetic products to customers incidental to other services. (vi) Trade shows and other venues where cosmetic product samples are provided free of charge. (vii) An establishment that manufactures or processes cosmetic products that are solely for use in research or evaluation, including for production testing, and not offered for retail sale.
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FEI	FDA Establishment Identifier
FPLA	Fair Packaging and Labeling Act
Manufacturing or Processing of a Cosmetic Product	Means engaging in one or more steps in the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product.[1]
MoCRA	Modernization of Cosmetics Regulation Act of 2022
Operator	Means a person who has management authority over an establishment.
Owner	Means a person who has an ownership interest in an establishment.
Responsible Person	As defined in section 604(4) of the FDCA, means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of the FDCA or section 4(a) of the Fair Packaging and Labeling Act.
Small Businesses	As defined in section 612 of the FDCA, means responsible persons, and owners and operators of facilities, whose average gross annual sales in the U.S. of cosmetic products for the previous 3-year period is less than $1,000,000, adjusted for inflation, and who do not engage in the manufacturing or processing of certain cosmetic products described in section 612(b) of the FDCA. A small business is exempt from the registration and listing requirements. Under section 612(b) of the FDCA, regardless of their average gross annual sales, businesses that engage in the manufacturing or processing of the following are not exempt from the registration and listing requirements: (i) Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual. (ii) Cosmetic products that are injected.

[1] PCPC is advocating in our draft guidance comments that this definition should not include "manipulation, sampling, testing, or control procedures" as these activities are specifically exempted by MoCRA from registration requirements.

Term	Definition
	(iii) Cosmetic products that are intended for internal use. (iv) Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual.
U.S. Agent	FDA has not defined this term in its draft guidance for cosmetics. Where the FDCA has similar requirements of other product categories, FDA requires U.S. agents to be a person or business entity that resides in the U.S. or maintains a U.S. place of business and is physically present in the U.S. See 21 CFR 1.227 (food) & 207.69 (human drugs). A U.S. agent may not be a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

C. Facility Registration Requirements

MoCRA requires registration with the FDA by December 29, 2023 for facilities that were, as of December 29, 2022, engaged in the manufacturing or processing of a cosmetic product for distribution in the U.S. For facilities first engaging in these activities after December 29, 2022, MoCRA requires registration with FDA within 60 days of such facility first engaging in these activities, or by February 27, 2024, whichever is later.

The facility owner or operator must ensure that such registration is made either by itself or by any responsible person whose cosmetic products are manufactured or processed at such facility. Each registration must be updated within 60 days of any changes to the information required for registration. This includes any changes that result in cancellation of the registration. Each registration must be renewed biennially (i.e., every two years). See FDCA Sec. 607(a).

Filers must have a facility registration number (i.e., an FEI) before starting the registration submission. Companies should first check the FEI Search Portal[2] to see if the facility already has an FEI. If no FEI exists for a facility, a company can obtain one by submitting a request to feiportal@fda.hhs.gov.

Facilities exempt from FDA's cosmetic facility registration requirement include a:

- Facility owner or operator that is a small business. See FDCA Sec. 612.
- Facility that does not manufacture or process any cosmetic products for distribution in the U.S. See FDCA Sec. 607(a).
- Facility that only manufactures or processes cosmetic products that are also drugs or devices. But note that the drug and/or device facility registration requirements under chapter V of the FDCA may still apply. See FDCA Sec. 613.

The facility registration requirement applies to both domestic and foreign facilities.

The FDA Commissioner may suspend a cosmetic facility registration following a determination that a cosmetic product manufactured or processed by a registered facility and distributed in the U.S. has a reasonable probability of causing serious adverse health consequences or death to humans and a reasonable belief that other products manufactured or processed by the facility may be similarly affected because of an issue

[2] https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login

that is sufficiently pervasive to extend across products. The suspension of a cosmetic facility registration is a decision that can be made only by the FDA Commissioner. If the facility registration is suspended, no person shall introduce or deliver cosmetic products from that facility into U.S. commerce. Before suspending a facility, FDA must notify the registrant or responsible person of its intent to suspend its registration, provide the basis for the suspension, and provide the registrant or responsible person 5 business days to provide a plan to address FDA's reasons for suspension. If FDA issues an order for suspension, it must provide the registrant or responsible person an opportunity to an informal hearing on the actions required to reinstate the registration.

D. Product Listing Requirements

In general, MoCRA requires each cosmetic product to be listed with FDA within 120 days after such cosmetic product is marketed in U.S. interstate commerce. A cosmetic product that was marketed as of December 29, 2022 must be listed by December 29, 2023. FDA requires the listing of a cosmetic product first marketed after December 29, 2022 to be submitted within 120 days or marketing the product, or by April 27, 2024, whichever is later.

The responsible person must ensure that such listing is made either by itself or by another entity (e.g., contract manufacturer, consultant, etc.) and must provide updates to cosmetic product listing information annually. This includes requiring a listing update if and when a product is discontinued. See FDCA Sec. 607I. FDA will provide an abbreviated process for renewal of any cosmetic product listing for which there has been no change in the product listing information. See FDCA Sec. 607(c)(3).

The entity submitting a cosmetic product listing will need to obtain the relevant facility registration number(s) (FEI) for each facility where a cosmetic product is manufactured or processed because the facility registration number(s) is required for the product listing submission. If the facility is exempt from registration (e.g., small business, etc.) and has no facility registration number, then the facility name/address can be provided instead.

Exemptions from FDA's cosmetic product listing requirement include:

- Cosmetic products from a responsible person that is a small business. See FDCA Sec. 612.
- A cosmetic product that is not marketed for U.S. interstate commerce. See FDCA Sec. 607(c). (Absent future guidance from FDA stating otherwise, interstate commerce generally includes products manufactured in the U.S. and exported.)
- A cosmetic product that is also a drug or device. But note that FDA's drug and/or device listing requirements under chapter V of the FDCA may still apply. See FDCA 613.

Foreign responsible persons are not exempt.

II. CHECKLIST

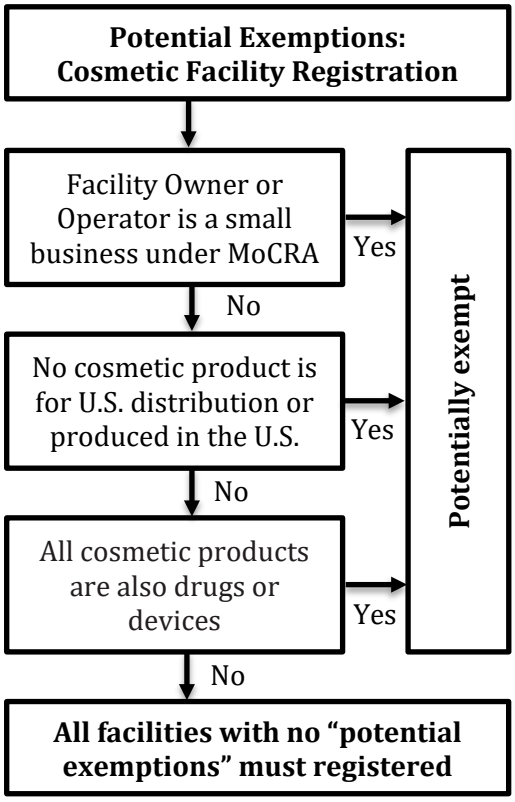
A. Scope

The following charts are intended to reflect the obligations under MoCRA that companies must consider in order to be compliant with the registration and listing components of the new law.

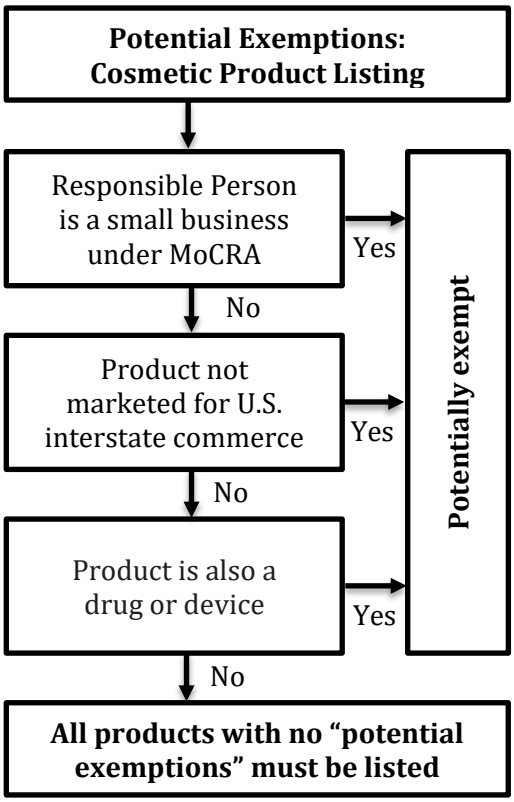
B. Potential Exemptions

These charts may help ascertain which cosmetic facilities and products must be registered or listed under MoCRA:

Facility Owner or Operator:
Office Address:
Facility Physical Address:
☐ Must be registered or ☐ Exempt
☐ Must be registered or ☐ Exempt
☐ Must be registered or ☐ Exempt



Responsible Person:
Office Address:
Cosmetic Products or Brand Names:
☐ Must be listed or ☐ Exempt
☐ Must be listed or ☐ Exempt
☐ Must be listed or ☐ Exempt



C. MoCRA Requirements for Consideration

The following items are MoCRA requirements for which interested parties may want to consider designating specific responsibility (for instance, "Party A" versus "Party B" in the below). The requirements have been grouped by category below.

Changes to the Potential Exemptions				
Responsibilities			**N/A**	**Conditions**
Notify the other party of any change to the potential exemptions in *Sec. II.B.* and effective date	☐	☐	☐	Within ___ days after any change to the potential exemptions. (1-59 days)

Facility Registration				
Responsibilities			**N/A**	**Conditions**
If the facility does not already have an FEI number (confirm online first), request from FDA at feiportal@fda.hhs.gov (FDA has estimated that it takes 10-15 business days to process an FEI request)	☐	☐	☐	Within ___ days after such facility first engages in the manufacturing or processing of a cosmetic product for U.S. distribution.
Register with FDA the facility(s) with no potential exemptions in Sec. II.B.	☐	☐	☐	Within 60 days after such facility first engages in the manufacturing or processing of a cosmetic product for U.S. distribution.
Update registrations	☐	☐	☐	Within 60 days of any changes to the information required.
Renew registrations	☐	☐	☐	Before the biennial deadline.
Share with the other party:				Within ___ days before the initial registration deadline. (1-59 days) If there are changes to information required, within ___ days before the update deadline, and within ___ days before the renewal deadline. (1-59 days)
1. The name of the owner and/or operator of the facility;	☐	☐	☐	
2. The facility's name, physical address, email address, and telephone number;	☐	☐	☐	
3. With respect to any foreign facility, the contact for the U.S. agent of the facility (name and phone number), and, if available, the electronic contact information (email);	☐	☐	☐	
4. FEI number;	☐	☐	☐	

Facility Registration				
Responsibilities			**N/A**	**Conditions**
5. All brand names under which cosmetic products manufactured or processed in the facility are sold;	☐	☐	☐	
6. The product category or categories and responsible person for each cosmetic product manufactured or processed at the facility; and	☐	☐	☐	
7. Type of submission (initial, amended, biennial renewal, or abbreviated renewal).	☐	☐	☐	
Optional fields:				
1. Parent company name (if applicable);	☐	☐	☐	
2. Facility DUNS Number; and	☐	☐	☐	
3. Additional contact information for individuals associated with the registration	☐	☐	☐	
Confirm to the other party:				Within ____ days after effective date of initial registration, update, and renewal.
1. Registration of each facility; and	☐	☐	☐	
2. Date registered	☐	☐	☐	
Alert the other party if FDA sends a notice of suspension, hearing on suspension, post-hearing corrective action plan, reinstatement, or suspension.	☐	☐	☐	Within __ business days after receiving each FDA communication. (1-4 business days)

Cosmetic Product Listing				
Responsibilities			**N/A**	**Conditions**
List with FDA the cosmetic product(s) with no potential exemptions in Sec. II.B.	☐	☐	☐	Within 120 days of marketing such product in U.S. interstate commerce.
Renew listings	☐	☐	☐	Before the annual deadline.

Cosmetic Product Listing				
Responsibilities			**N/A**	**Conditions**
Share with the other party:				Within ___ days before the initial listing deadline. (1-119 days) If there are changes to information required, within ___ days before the renewal deadline. (1-364 days)
1. FEI number of each facility where the cosmetic product is manufactured or processed;	☐	☐	☐	
2. The name and contact number of the responsible person and the name for the cosmetic product, as such name appears on the label;	☐	☐	☐	
3. The applicable cosmetic category or categories for the cosmetic product;	☐	☐	☐	
4. A list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by the name, as required under 21 CFR 701.3, or by the common or usual name of the ingredient;	☐	☐	☐	
5. The product listing number, if any previously assigned; and	☐	☐	☐	
6. Type of submission (initial, update to content (annual), abbreviated renewal).	☐	☐	☐	
Optional fields:				
1. Parent company name (if applicable);	☐	☐	☐	
2. Type of business (as listed on the label), i.e., manufacturer, packer, or distributor;	☐	☐	☐	
3. Image of the label;	☐	☐	☐	
4. Product webpage link;	☐	☐	☐	
5. Whether the cosmetic product is for professional use only;	☐	☐	☐	
6. Responsible person DUNS Number for address listed on product label;	☐	☐	☐	
7. UNIIs; and	☐	☐	☐	

Cosmetic Product Listing				
Responsibilities			**N/A**	**Conditions**
8. Additional contact information for individuals associated with the listing.	☐	☐	☐	
Confirm to the other party:				Within ___ days after effective date of initial listing and renewal.
1. Listing of each cosmetic product;	☐	☐	☐	
2. Product listing number; and	☐	☐	☐	
3. Date listed.	☐	☐	☐	

D. Information Sharing

The following is a list of information that must be submitted to the FDA under the various provisions of MoCRA. This information thus may need to be shared between entities where one entity is submitting information on behalf of another entity for the purposes of MoCRA compliance.

FEI Number Request	
The legal name of the firm being registered.	
Are you representing the firm as an Agent (third party)?	
Any alternate firm names, including those used for "doing business as" purposes.[3]	
The physical address of the firm being registered.	
The designated mailing address for the firm being registered.[3]	
The name and contact information of the designated contact person at the facility being registered.	
A comprehensive list of activities conducted at this specific location (e.g., drug manufacturing, food packaging, etc.).	
Any registration numbers associated with other FDA Centers, if applicable.	
Any former names the firm was known by.[3]	
Any previous addresses linked to the firm.[3]	

[3] PCPC is advocating in our draft guidance comments that these fields should be optional.

Facility Registration	
The name of the owner and/or operator of the facility[3]	
The facility's name, physical address, email address, and telephone number[4]	
With respect to any foreign facility, the contact for the U.S. agent of the facility (name and phone number), and, if available, the electronic contact information (email)	
FEI number	
All brand names under which cosmetic products manufactured or processed in the facility are sold[4]	
The product category or categories for each cosmetic product manufactured or processed at the facility[4]	
The responsible person for each cosmetic product manufactured or processed at the facility[4]	
Type of submission (initial, amended, biennial renewal, or abbreviated renewal)	
(Optional) Parent company name (if applicable)	
(Optional) Facility DUNS Number	
(Optional) Additional contact information for individuals associated with the registration	

[4]PCPC is advocating in our draft guidance comments that FDA not require the re-entry of any information on the cosmetic facility registration form, associated with the FEI number on such form, which was or will be submitted to the Agency as part of a FEI request or cosmetic product listing.

Cosmetic Product Listing	
FEI number of each facility where the cosmetic product is manufactured or processed	
The name and contact number of the responsible person and the name for the cosmetic product, as such name appears on the label	
The applicable cosmetic category or categories for the cosmetic product	
A list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by the name, as required under 21 CFR 701.3, or by the common or usual name of the ingredient	
The product listing number, if any previously assigned	
Type of submission (initial, update to content (annual), abbreviated renewal)	
(Optional) Parent company name (if applicable)	
(Optional) Type of business (as listed on the label), i.e., manufacturer, packer, or distributor	
(Optional) Image of the label	
(Optional) Product webpage link	
(Optional) Whether the cosmetic product is for professional use only	
(Optional) Responsible person DUNS Number for address listed on product label	
(Optional) UNIIs	
(Optional) Additional contact information for individuals associated with the listing	