

New Responsibilities under MoCRA

New Responsibility	Effective Date	Spa De Soleil Responsibility	Client Responsibility (Responsible Person)
Manufacturing Facility Registration	Late 2023 / Early 2024	X	
Adherence to Good Manufacturing Practices (GMPs)	Late 2023 / Early 2024	X	
Designation of a "Responsible Person"	Late 2023 / Early 2024		X
Product Record Keeping -- keep and maintain records that include, at a minimum, batch records and unit counts for each SKU and distribution records	Late 2023 / Early 2024		X
Reporting of Serious Adverse Event -- report to the FDA serious injuries, significant aggregate minor injuries, or other reportable events as defined by the FDA that are suffered by users of the product	Late 2023 / Early 2024		X
Create, Maintain, Update Product Listings -- create and maintain an account with the FDA's upcoming online portal; account to be in the responsible person's name. Product listing will require (at a minimum) information about the product name, product ingredients, and the place of manufacture	Late 2023 / Early 2024		X
Product Safety Substantiation -- test or order testing and maintain documentation substantiating product safety for each cosmetic product	TBA		X
Product Label Requirements -- product label must identify all fragrance allergens present in the product and provide clear information whereby users can report serious adverse events	Late 2023 / Early 2024		X
Records Access -- FDA may access to all product records for review at any time	Late 2023 / Early 2024	X (manufacturer records)	X (all product records)

Projected Future Responsibilities

Projected Future Responsibility	Effective Date	Spa De Soleil Responsibility	Client Responsibility (Responsible Person)
<p>Fragrance Allergen Warnings / Disclosure Expected to be more expansive than simply providing the information on the label (the above rule). May be similar to the California Safe Cosmetics Program rule where the product must be registered in a separate database or have its listing flagged as containing fragrance allergens</p>	TBA		X
<p>Talc Testing New rule requiring all talc used in cosmetic products to be tested for asbestos and to maintain a record of testing showing asbestos content is below a certain threshold</p>	TBA		X
<p>PFAS Testing New rule may prohibit or limit PFAS ingredients in products. It is not clear if this rule applies only to intentionally added PFAS ingredients or if testing is required to show that unintentional PFAS adulterants are below a stated threshold</p>	TBA		X

NOTE: the above tables are provided merely as a courtesy. Spa de Soleil made efforts to ensure the information presented above is complete and accurate at the time this document was created, but Spa de Soleil accepts no responsibility for any incomplete and inaccurate information. Do not rely on the information listed above. Consult with an attorney or a qualified compliance specialist to determine your company's exact responsibilities under the law.