Modernization of Cosmetics Regulation Act of 2022 (MoCRA)

Activities / Time line	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24	May-24	Jun-24	– –	– –	Dec-24	Jan-25	– –	– –	Dec-25	2026	– –
Existing Facility Registration	***Preparatory Phase***				29th															
New Facility Registration (a facility engaged in manufacturing of Cosmetics for distribution in the U.S. after December 29, 2022)	1. FDA Establishment Identifier (FEI)* submission through FDA online portal						27th													
Amendment to Facility Registration / Cancellation	2. Check for Facility and Responsible person DUNS Number for address listed on product label (optional for now)						Within 60 days of any changes to the information required for registration													
Renewal of Facility Registration	3. Assign Responsible Person (U.S. based)																	Every two years		
Existing Product Listing	4. Collect details of all U.S. marketed products manufactured in a facility				29th															
New Product Listing (Product that entered U.S. Market after December 29, 2022)									27th											
Renewal of Product Registration (including discontinuation)	5. Develop list of ingredients in the cosmetic product, including any fragrances, flavours, or colors													Annually						
Labelling Contact Information (Responsible Person)	6. Collect Unique Ingredient Identifiers (UNIIs) for product composition																			
Labelling Professional Use	7. Set-up Adverse Events Monitoring Procedure and Recall protocols/SOPs including insurance coverage																			
Labelling of Fragrance Allergen	8. Initiate Product Safety Assessment including Toxicological reports for Ingredients										Proposed rule				Final Rule					
Adverse Events Monitoring	9. Raw Material Documents (Specification, Composition, CoA, Declaration of conformity etc.)																			
Safety Substantiation (Responsible person is required to ensure and maintain records supporting adequate safety substantiation)																				
Asbestos in Talc-containing Cosmetics (Testing Method)	10. Review readiness for GMP in reference to ISO-22716 for now				Proposed rule & Comment period									Final Rule						
PFAs in Cosmetics (safety of the use of per- and polyfluoroalkyl substances in Cosmetics)																				
New GMP Rule														Proposed rule				Final rule		

U.S. FDA is developing an electronic submission portal to streamline submission and receipt of registration and product listing information (probably the portal will be up and live by October 2023).
FDA is also developing a paper form as an alternative submission tool.
* To facilitate the registration process, the owner or operator of a facility will need to obtain an FEI number before submitting the facility registration.