The Modernization of Cosmetics Regulation Act (MoCRA) Webinar

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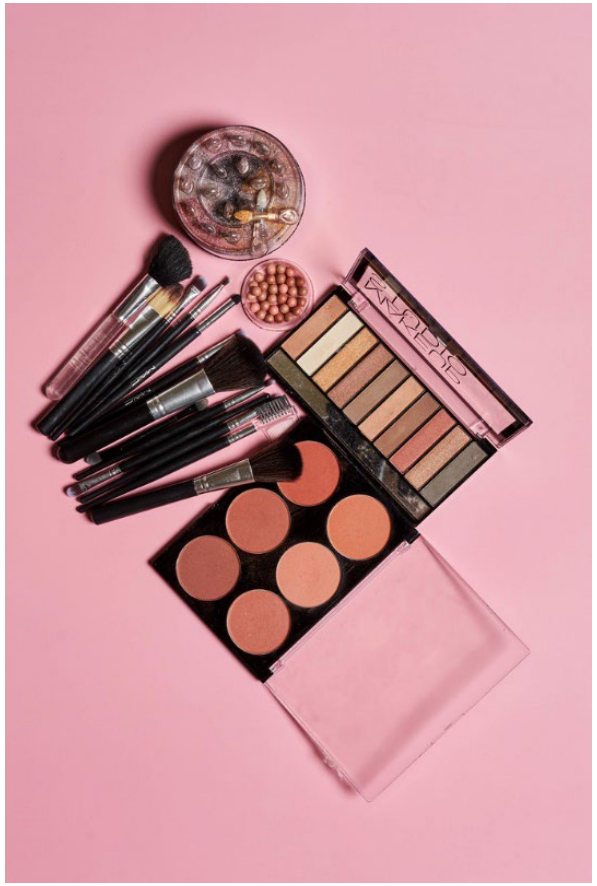
Agenda

- The Modernization of Cosmetics Regulation Act (MoCRA)
- Current Obligations and Upcoming Deadlines
- Other Things You Should be Thinking About:
  - Are you prepared not only to register and list but also to renew and update as appropriate?
  - Are your adverse event reporting procedures current?
  - Have you recently reviewed your safety and toxicity claims and the support therefore?
  - Have you reviewed your recall insurance coverage?
  - Do not forget about the private bar!

Modernization of Cosmetics Regulation Act of 2022 (MoCRA)

- MoCRA is the biggest change to the scope of FDA's regulatory authority over cosmetics since 1938
- The entire cosmetics supply chain will be affected by FDA's new regulatory authority
- The new cosmetics regulatory regime imposes:
  1. GMP standards
  2. Registration and listing requirements
     - FDA may suspend registrations
  3. Adverse event reporting requirements
  4. Mandatory recall authority
  5. New labeling requirements (e.g., address information, fragrance allergens).
- FDA to assess the safety of PFAS in cosmetic products



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Some Key Terms

Cosmetic Product – A preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product. (Section 604(2))

- Appendix A of the final *Registration and Listing of Cosmetic Product Facilities and Products* Guidance provides cosmetic product categories and codes. The list will be periodically updated
- If nothing "fits," use the product category and code that match most closely and use the "other" category and code if another does not appear to fit. See Appendix B re: eye products.

Facility – Any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States. (Section 604(3))

- Carve-outs include certain beauty shops and salons, certain retailers, hospitals, public health agencies, trade shows, certain research and testing facilities, and
- Establishments that only perform one or more of the following with respect to cosmetic products: labeling, relabeling, packaging, repackaging, holding, and distributing

Responsible Person – The manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of the cosmetic product. (Section 604(4))

MoCRA Deadlines

MoCRA Requirement	Current Deadline
Safety Substantiation	In effect
Adverse Events Reporting (and related recordkeeping and follow-up reporting)	In effect
Labeling - Professional Use	In effect
Register (covered cosmetic manufacturing or processing facilities and renew/update as appropriate)	July 1, 2024
List (covered cosmetic products, including their ingredients, and update annually)	July 1, 2024
Labeling - Contact Information (certain contact information for the responsible person must be on the label)	December 29, 2024

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MoCRA Deadlines (cont.)

Required Rulemaking	Publication Deadline for Proposed Rule	Publication Deadline for Final Rule
Good Manufacturing Practice (GMP) regulations	December 29, 2024 **(We anticipate a delay)**	December 29, 2025 **(We anticipate a delay)**
Establishing and requiring standardized testing methods for detecting asbestos in talc-containing cosmetic products	December 29, 2023 **(Delayed)**	180 days after the proposed rulemaking's public comment period closes
The identification of fragrance allergens to be listed on cosmetic products labels	June 29, 2024 **(We anticipate a delay)**	180 days after the proposed rulemaking's public comment period closes

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Our Recent Alerts on MoCRA

FDA Finalizes Section V of the 2016 Revised Draft NDI Guidance – March 2024

FDA Launches Cosmetics Direct, Issues Final Guidance on Registration and Listing of Cosmetic Product Facilities and Products Under MoCRA, and Updates Instructions for Serious Adverse Event Reporting for Cosmetic Products – December 2023

FDA Delays Enforcement of MoCRA's Registration and Listing Requirements for Six Months - November 2023

Prepare Now for the New FDA Requirements for Cosmetics Companies – July 2023

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Questions? Contact Us

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