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FDA Seeks Comments on Updates to MoCRA Guidance on Registration, Listing of Cosmetic Product Facilities

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On December 11, 2024, the US Food and Drug Administration (FDA) updated its Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products. As discussed in our previous *On the Subject*, FDA released the original version of the final guidance in December 2023 as required by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). MoCRA introduced several new requirements for cosmetic product facilities, and the final guidance provided key information about who must register, what information is required, how and when to submit information, and available exemptions. The final guidance also included frequently asked questions (FAQs) in Appendix B, designed to help industry stakeholders understand and comply with MoCRA requirements, which the FDA began enforcing on July 1, 2024.

The updated guidance builds on the earlier issued guidance, with the addition of new registration and listing FAQs. FDA has solicited comments about the updates to the guidance by January 13, 2025.

In Depth

MoCRA, signed into law in 2023, introduced new requirements for cosmetic companies, including:

- Facility registration and product listing
- Good manufacturing practices (GMPs)
- Safety data and adverse event reporting
- Labeling requirements (domestic contact information, allergens, and professional use labels).

Most importantly, under MoCRA, FDA has enhanced enforcement powers, such as inspecting facilities, requesting recalls, and suspending registrations if products pose significant health risks.

KEY MoCRA DEADLINES

- **Facility registration and product listing:** July 1, 2024.
- **Update responsible person contact information:** December 29, 2024.
- **FDA GMP regulations and PFAs report:** December 29, 2025.

KEY DEFINITIONS

The updated FAQs use the following definitions regarding the implementation of the registration and product listing requirements of Section 607 under the Food, Drug, and Cosmetic Act:

- **US agent:** A US-based individual or entity acting as FDA contact for foreign facilities.
- **FEI:** FDA establishment identifier, a unique registration number for facilities.
- **Cosmetic product:** A specific preparation of cosmetic ingredients for a finished product.
- **Facility:** Any establishment that manufactures or processes cosmetic products distributed in the United States.

FAQs

FDA added three FAQs in Appendix B of the guidance. These three new FAQs are open to comments from stakeholders. While FDA will accept comments on any guidance document at any time, it requested comments on the new FAQs by January 13, 2025.

Below are concise summaries of the new FAQs; for further detail, please consult Appendix B of the updated guidance.

20. What are the responsibilities of a US agent?

- Assist FDA in communications with the foreign establishment.
- Respond to questions about the foreign establishment’s products imported into the US.
- Help FDA schedule inspections of the foreign establishment.
- Receive information or documents from FDA on behalf of the foreign establishment when direct contact is not possible.

21. Can nearby buildings share one FEI number?

- Multiple buildings within three miles of one another can share one FEI number if they are part of the same business, are under the same local management, and can be inspected together.
- The cosmetic product facility registration system allows one registration per FEI number, even

if it includes multiple buildings.

22. Do free samples or gifts require product listing?

- Yes, generally. A product listing must be submitted for each cosmetic product, including free samples or gifts.
- Exemptions apply for samples provided for research and development or within the industry, not intended for consumer use.

KEY TAKEAWAYS

FDA’s addition of three new FAQs to the final guidance offers an opportunity for stakeholders to provide feedback on MoCRA implementation. Comments on these updates should be submitted by January 13, 2025.

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