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ALERT

FDA Updates Final Guidance on Cosmetic Facility Registration and Product Listing

January 8, 2025

The Food and Drug Administration (FDA) recently issued a Notice announcing the availability of an updated final guidance for the industry entitled "Registration and Listing of Cosmetic Product Facilities and Products." The guidance, released December 12, 2024, provides non-binding recommendations and instructions to assist persons submitting cosmetic product facility registrations and product listings to FDA, as required by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).

The updated guidance finalizes the frequently asked questions and answers (FAQs) section in new Appendix B, and includes three new proposed questions and answers for comment. In a less than jovial move during the holiday season, FDA requested comments by **January 13, 2025.** However, the Regulations.gov docket states that FDA will be "allowing late comments."

Background

On December 29, 2022, President Biden signed the "Consolidated Appropriations Act, 2023" into law, which included MoCRA. Pub. L. 117-328. Among other provisions, MoCRA added Section 607 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing requirements for cosmetic product facility registration and cosmetic product listing. Section 607(a) of the FD&C Act requires every person who owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility. 21 U.S.C. 364c(a). In addition to the registration requirements, Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person must submit to FDA "a cosmetic product listing." Certain small businesses, as defined in

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Section 612 of the FD&C Act, are exempt from the registration and listing requirements. 21 U.S.C. 364h. Compliance with these requirements went into effect in July 2024. See our prior alert summarizing the facility registration and product listing requirements here.

What's New in the Guidance?

a. Finalized FAQs in Appendix B

FDA first issued a final version of this guidance on December 19, 2023, and at the same time included a draft FAQs section, Appendix B, for comment purposes only. The recently updated guidance finalizes Appendix B and includes a few editorial and clarifying changes to the previous guidance version. While the guidance did add eye shadow as a cosmetic that is likely to come into contact with the mucus membrane of the eye in Question 6, and added tattoo ink as a cosmetic intended to alter the appearance for more than 24 hours in Question 7, the updated final document is generally unchanged aside from the three new proposed questions.

b. Three New Proposed Questions and Answers

The three proposed FAQs in Appendix B, questions 20 through 22, are reproduced below:

Question 20: What are the responsibilities of a U.S. Agent?

> **Answer:** The responsibilities of the U.S. agent are limited and generally include:
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> • Assisting FDA in communications with the foreign establishment;
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> • Responding to questions concerning the foreign establishment's products that are imported or offered for import into the United States;
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> • Assisting FDA in scheduling inspections of the foreign establishment; and
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> • Receiving information or documents from FDA on behalf of the foreign establishment when FDA is unable to contact the foreign establishment directly or expeditiously. FDA providing such information or documents to the U.S. Agent will be considered equivalent to providing the same information or documents to the foreign establishment. (We also note that FDA does not recommend or endorse any particular U.S. agent.)

Question 21: Can multiple buildings that are in close proximity (within 3 miles of each other) be associated with one FEI number, or are two FEI numbers needed?

> **Answer:** A cosmetic product facility may include multiple buildings that are part of the same establishment. Under certain circumstances, one FEI number may be associated with multiple buildings that manufacture or process cosmetic products. Multiple buildings with different physical addresses that are within three miles of one another are generally considered one establishment with one FEI number if their activities are closely related to the same business enterprise; are under the supervision of the same

local management; and are capable of being inspected by FDA during a single inspection. The cosmetic product facility registration and listing system allows only one cosmetic facility registration to be associated with a single FEI number. A cosmetic product facility registration may be submitted for multiple buildings that are associated with the same FEI number, and the physical address listed with the cosmetic product facility registration needs to match the "Physical Address" that is listed in the FEI Search Portal.

Note: FEI registration and cosmetic product facility registration are two separate registration processes. Registering for and obtaining the FEI number must be completed before starting the cosmetic product facility registration submission.

Question 22: Does a product listing need to be submitted for free samples or gifts?

Answer: Generally, yes. Under Section 607(c) of the FD&C Act, the responsible person must submit to FDA a cosmetic product listing for each cosmetic product. While, under Section 604(3) of the FD&C Act, the definition of "facility" includes exemptions for trade shows and other venues where cosmetic product samples are provided free of charge and entities that provide complimentary cosmetic products to customers incidental to other services, which are relevant for cosmetic product facility registration, the requirement to submit a cosmetic product listing still applies to these types of cosmetic products. Thus, the responsible person for each cosmetic product, even those provided as free samples or gifts, must submit a cosmetic product listing in accordance with Section 607(c) of the FD&C Act, unless another exemption applies (see, e.g., Section 612 of the FD&C Act). However, the FDA does not expect this requirement to apply to samples that are provided within the industry for purposes of research and development or product development and not intended for consumption by the consumer – for example, free finished product samples to hand out to industry participants (see Q1 and Section 607(c) of the FD&C Act).

ICYMI – July 2024 Update to Cosmetic Direct

In case you missed this related cosmetic news, on July 29, 2024, FDA updated its product listing functions in Cosmetic Direct with a new function intended to ease the burden associated with drug product listings; specifically, the new function allows relisting of previously "discontinued" cosmetic products. In order for a responsible person to take advantage of this feature, it is important to select the "Discontinue Product" tab rather than the "Delete" tab, as the latter permanently removes the cosmetic product from the FDA system.

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As noted above, the comment period related to the guidance closes next week. However, FDA is suggesting it will allow submission of late comments. Please do not hesitate to reach out to the authors of this alert if you have any questions regarding the facility registration or product listing requirements, or you have an interest in commenting and require assistance in developing such comments.