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FDA Publishes Draft Guidance on Cosmetic Product Facility Registration and Cosmetic Product Listing

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On August 7, 2023, the Food and Drug Administration (FDA) published Draft Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products (the Draft Guidance), which provides much-needed clarifications to the registration and listing requirements that will soon apply to cosmetics companies under the Modernization of Cosmetics Regulation Act (MoCRA), for review and public comment. MoCRA was signed into law in December 2022 (see our prior post here) and added significant new provisions on cosmetic products to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under Section 607 of the amended FD&C Act, facilities that manufacture or process a cosmetic product for distribution in the United States must register with FDA and submit a cosmetic product listing, and the Draft Guidance answers basic and essential questions about who must register and list, what information must be included, and how to submit information to FDA.

This post summarizes key takeaways from the Draft Guidance and discusses its implications as the December 29, 2023 initial registration and listing deadline approaches.

Newly Defined Terms Included in Draft Guidance

While many terms relevant to cosmetic products and facilities are already defined in the FD&C Act (including the recently added MoCRA provisions)—and unsurprisingly, FDA is not modifying such definitions—the Draft Guidance provides some new definitions that FDA plans to use for terms, such as Owner, Operator, Contract Manufacturer, and DUNS Number, which are specifically relevant to the registration and listing process. Operators and owners of facilities engaged in manufacturing or processing cosmetic products for distribution in the United States must register such facilities. However, the Draft Guidance does not explain what constitutes “management authority” for operators, nor does it elaborate upon what kinds of “ownership interest” (i.e. direct or indirect) bind an owner to the facility registration requirements.

Information to Submit in Facility Registration and Product Listing

The Draft Guidance recapitulates all of the information to be included with registration and product listing submissions to FDA, with the addition that the submitter must indicate the type of submission:

for registrations, initial, amended, biennial renewal, or abbreviated renewal; and for listings, initial, update to content, or abbreviated renewal. Helpfully, FDA clarifies that a facility owner, operator, or responsible person will need to obtain an FDA Establishment Identifier (FEI) number before starting the registration submission.

In addition to the basic information, FDA also requests that submitters provide the following optional information with a facility registration: the parent company name (if applicable), facility DUNS Number, and additional contact information for individuals associated with the registration. The following optional information may also be submitted with the product listing: the parent company name (if applicable), type of business, image of the label, product webpage link, whether the cosmetic product is for professional use only, the responsible person DUNS number for the address listed on the product label, Unique Ingredient Identifiers, and additional contact information for persons associated with the listing.

Both the facility registration and the product listing must include the applicable cosmetic product categories and codes, and Appendix A of the Draft Guidance provides a list of the 17 categories and individual codes.

Importantly, the Draft Guidance also specifies that no fee will be assessed for the submission of a cosmetic facility registration or product listing.

Public Disclosure of Facility Registration and Cosmetic Product Listing

The Draft Guidance also addresses which information from a product facility registration and cosmetic product listing FDA will not make available for public disclosure (i.e., through the Freedom of Information Act or a publicly available database on the agency's website). According to the Draft Guidance, FDA will not disclose the product listing number or the brand names identified in a registration under which cosmetic products manufactured or processed in the registered facility are sold. Likewise, the agency will not disclose information from a product listing on the registration number of the facility where the cosmetic product is manufactured or processed. However, all other information from a cosmetic product facility registration and listing will be available for disclosure to the public, and FDA plans to publish relevant information from both registrations and listings.

Pilot Program for Testing FDA's Electronic Submissions Portal

In conjunction with the Draft Guidance, FDA published a Federal Register notice seeking applications for a pilot program to test and evaluate the electronic portal cosmetic registration and listing. The purpose of the pilot program, which will be conducted by FDA's Office of Cosmetics and Colors (OCAC) and the Office of the Chief Scientist (OCS), is to evaluate the agency's new cosmetic product facility registration and listing electronic submission system. Though electronic submission is not required, and FDA will be developing a companion paper form for enrollment, FDA strongly encourages electronic submission.

FDA will select no more than nine participants, hopefully providing a representative cross-section of the cosmetic product industry, for the pilot program. The participants must be entities that will be required, under MoCRA, to submit cosmetic product facility registration and listing information and must be willing to provide feedback to the agency regarding the electronic submission process. Those who participate in the pilot program will receive training on the portal, submit simulated registration and product listing information to the portal, and provide feedback during the training process and following the simulated submissions. Entities willing to participate should submit a

statement of interest containing the information described in Section III of the Federal Register notice to eRLC.testing@fda.hhs.gov by August 22, 2023.

Conclusion

The Draft Guidance is the first of its kind that the FDA has published concerning MoCRA's requirements. Comments on the Draft Guidance can be submitted to the docket (Docket No. FDA-2023-D-1716) through September 7, 2023. According to the Draft Guidance, FDA's goal is for the new electronic submission portal to be available for use sometime in October 2023. As the deadline for facility registration and product listing approaches, we will continue to monitor the feedback FDA receives from both the comments to the docket and from participants in the pilot program, as well as any suggested changes the agency incorporates into its guidance.

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