Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing

Guidance for Industry

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I. INTRODUCTION

This guidance is intended to assist owners or operators of cosmetic product facilities that are subject to the requirements related to facility registration and responsible persons that are subject to the requirements related to cosmetic product listing under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance document discusses FDA's compliance policy for these requirements. FDA intends to delay enforcement of these requirements for six months to help ensure that industry has sufficient time to submit facility registration and product listing information.

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate. 21 CFR 10.115(g)(2). This guidance is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices. 21 CFR 10.115(g)(5).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. BACKGROUND

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) into law, which included the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). Among other provisions, MoCRA added section 607 to the FD&C Act (21 U.S.C. 364c), establishing requirements for cosmetic product facility registration and cosmetic product listing.

[1] This guidance has been prepared by the Office of the Chief Scientist (OCS) in cooperation with the Office of Cosmetics and Colors (OCAC)/Center for Food Safety and Applied Nutrition (CFSAN) at the Food and Drug Administration.

Section 607(a) of the FD&C Act requires every person that owns or operates a facility[2] that "engages in the manufacturing or processing of a cosmetic product for distribution in the United States" to register each facility with FDA. Section 607(a)(1)(A) provides that owners or operators of facilities engaged in the manufacturing or processing of a cosmetic product on December 29, 2022, must register each facility no later than December 29, 2023. Owners or operators of facilities that first engage in manufacturing or processing a cosmetic product after December 29, 2022, must register such facilities within 60 days of first engaging in such activity or by February 27, 2024, whichever is later (Section 607(a)(1)(B)).

Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person[3] must submit to FDA "a cosmetic product listing" or ensure that such submission is made. Section 607(c)(2) of the FD&C Act provides that the responsible person for a cosmetic product that was marketed on December 29, 2022, must submit a cosmetic product listing, no later than December 29, 2023, or for a cosmetic product that is first marketed after December 29, 2022, within 120 days of distributing such product in interstate commerce.

Certain small businesses, as defined in section 612 of the FD&C Act (21 U.S.C. 364h), are not required to register facilities and list cosmetic product(s). In addition, a facility is not required to register if it is also subject to the requirements in chapter V of the FD&C Act (for drugs and devices) unless the facility also manufactures or processes cosmetic products that are not subject to the requirements of chapter V of the FD&C Act (see section 613 of the FD&C Act (21 U.S.C. 364i)). A cosmetic product does not need to be listed if it is also subject to the requirements in chapter V of the FD&C Act (for drugs and devices).

FDA issued a draft guidance entitled "Registration and Listing of Cosmetic Product Facilities and Products" on August 8, 2023 (88 FR 53490). The draft guidance, when finalized, will provide recommendations and instructions to assist persons submitting cosmetic product facility registrations and product listings to FDA.

FDA is also developing an electronic submission portal, Cosmetics Direct, to streamline submission and receipt of facility registration and product listing information under section 607 of the FD&C Act, and is developing paper forms (FDA Form 5066 and 5067) as an alternative submission tool. FDA will conduct a pilot program to ensure that the new electronic submission portal is functional and usable so that industry will be able to meet its statutory obligations. As another alternative, users may transmit SPL-formatted submissions through FDA's Electronic Submissions Gateway (ESG),[4] or any SPL authoring software including Xforms.[5] FDA strongly encourages electronic submissions to facilitate efficiency and timeliness of data submission and management for the agency. FDA anticipates that electronic submission, technical assistance documents, and paper submission forms will be available in early December 2023.

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[2] The term "facility" is defined in section 604(3) of the FD&C Act (21 U.S.C. 364(3)).
[3] The term "responsible person" is defined in section 604(4) of the FD&C Act (21 U.S.C. 364(4)).
[4] For more information on FDA's Electronic Submissions Gateway, please refer to the webpage at https://www.fda.gov/industry/electronic-submissions-gateway.
[5] For more information on Xforms, please refer to the webpage at https://www.fda.gov/industry/structured-product-labeling-resources/spl-xforms. In addition, the technical details on using SPL for cosmetic product facility registration and product listing will be available in the FDA's SPL Implementation Guide with Validation Procedures available at https://www.fda.gov/media/84201/download.

III. DISCUSSION

FDA will be ready to accept registration and listing information by the statutory deadline of December 29, 2023, and we encourage companies to meet that deadline if they are able to do so. However, FDA does not intend to enforce the requirements under section 607 of the FD&C Act related to cosmetic product facility registration and cosmetic product listing for an additional six months after the December 29, 2023, statutory deadline, or until **July 1, 2024,** to provide regulated industry additional time to comply with these requirements. In addition, FDA does not intend to enforce the registration requirement for owners or operators of facilities that first engaged in manufacturing or processing a cosmetic product after December 29, 2022, or the listing requirement for cosmetic products first marketed after December 29, 2022, until **July 1, 2024**.

FDA intends to delay enforcement of the cosmetic product facility registration and product listing requirements. Industry has expressed concerns that they need additional time, for example to gather the relevant information required for facility registration and product listing, including obtaining facility registration numbers to associate with cosmetic product listings, obtain access to the electronic submissions database, and enter and submit accurate registration and listing information.