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Locke Lord QuickStudy: FDA Announces Public Meeting ?Concerning Good Manufacturing Practices for Cosmetic ??Products

Locke Lord LLP

The recently enacted Modernization of Cosmetics Regulation Act of 2022 ("MoCRA") requires FDA to adopt regulations governing Good Manufacturing Practices ("GMPs") for the manufacture of cosmetic products and ingredients. H.R. 2617—1392 (2022). Newly added Section 606(c) of the Federal Food, Drug, and Cosmetics Act ("FDCA") provides FDA a deadline of two years after enactment (December 29, 2024) to publish proposed regulations for comment and three years after enactment (December 29, 2025) for issuing GMPs as final rules.

On April 26, 2023, FDA announced that it would be holding a public meeting on **June 1, 2023** in the form of a virtual listening session to consult industry stakeholders, consumer organizations, and other experts regarding what issues it should consider when proposing GMPs. (April 26, 2023 FDA Announcement.) In the announcement, FDA invited industry stakeholders and the general public to register by **6:00 pm ET** on **May 18, 2023** if they wish to present comments at the meetings, which are limited to three minutes. (*Id*.) Any selected speakers will be required to submit presentation materials in .pdf format by **May 22, 2023**. (*Id*.)

At that same time, FDA also announced that it had established a docket on regulations.gov to accept written comments and proposals on the issue that would be open until **July 3, 2023** (Docket No. FDA-2023-N-1466).

For those interested in participating in the public meeting or submitting written comments, FDA has identified several issues of interest that it would like comments to address if possible, which include: (1) any national or international standards (*e.g.* ISOs) that are already in use or being considered for use in the industry; (2) what types of requirements in other GMPs or standards may cause undue burdens when applied to cosmetics; (3) what flexibility in GMPs is necessary to address the different scales of production in the cosmetics industry; (4) whether and how to adjust requirements for small businesses to avoid undue hardships; (5) appropriate compliance times for GMPs; (6) what costs are associated with adoption of GMPs by the industry; (7) examples of adverse events that can be traced to manufacturing practices and what GMPs may be useful in future avoidance; and (8) how and whether implementing GMPs for cosmetic products will have an actual effect on consumer safety. Each of these issues requires significant input and contemplation from both FDA and stakeholders before final rules can be adopted.

The public meeting and docket will provide industry stakeholders their first real opportunity to address FDA about challenges they perceive the industry will face in adopting a formal set of GMPs. Once FDA issues final GMPs, the entire cosmetics industry will be subject to the rules FDA's new enforcement powers granted by MoCRA. (Locke Lord QuickStudy: Amendments to Section VI of the Federal Food, Drug, and Cosmetics Act in the Omnibus Bill.) Thus, it will be important for key stakeholders to attend and participate in all steps of the rulemaking process starting with this initial meeting and docket.

Locke Lord’s FDA Regulatory and Cosmetics and Personal Care Industry teams will be closely monitoring FDA’s actions regarding GMPs and industry comments so that we can assist you with implementing whatever requirements will be needed to stay in compliance with FDA’s latest thoughts and requirements. Please feel free to contact Sharon Blinkoff to learn more.

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