Summary of Public Meeting on Good Manufacturing Practices June 1, 2023

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) added section 606 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), requiring FDA to establish by regulation good manufacturing practices (GMPs) for facilities. The FDA held this virtual listening session to consult cosmetics manufacturers, including smaller businesses, contract manufacturers, consumer organizations, and other experts to inform FDA's efforts in developing these GMPs.

FDA heard from approximately 50 public speakers representing cosmetics manufacturers, contract manufacturers, laboratories, and academia as well as nonprofit organizations. These included speakers representing cosmetic businesses of different sizes and scopes, such as domestic and international businesses, and businesses also engaged in other industries such as for nonprescription drugs and dietary supplements.

To facilitate input, the FDA developed a series of topics covering the types of information that we were interested in obtaining. The key themes, perspectives, and ideas that speakers raised on these topics are summarized below; these summaries do not necessarily represent our viewpoints.

Topics Related to Good Manufacturing Practices

1. *Identify any national or international standard (e.g., International Organization for Standardization (ISO) standard 22716:2007) and the extent to which it would be practicable for good manufacturing practice regulations for cosmetic products to be consistent with such standard. Please include whether there are specific items in the standard which are perceived to be burdensome or for which a less burdensome alternative exists that would protect the public health and ensure that cosmetic products are not adulterated.*

   We heard that it is important for GMP regulations to be consistent with existing national and international standards for cosmetic GMPs. Many speakers supported adopting or considering consistency with the ISO 22716:2007 standard (Cosmetics—Good Manufacturing Practices (GMP)—Guidelines on Good Manufacturing Practices). Several speakers identified limitations in the ISO 22716:2007 standard, such as for water quality, raw materials, retained samples, or complaints; these speakers suggested adopting or considering consistency with other standards or guidelines that may address these limitations, such as the NSF International/American National Standards Institute 455-3-2022 Good Manufacturing Practices for Cosmetics standard (NSF/ANSI 455-3-2022) or FDA's 2013 "Cosmetic Good Manufacturing Practices" Draft Guidance (Cosmetic GMP Draft Guidance).

2. *Describe what constitutes sufficient flexibility within good manufacturing practices for cosmetic products to ensure regulations are practicable for all sizes and types of facilities to which such practices may apply. Please take into account the size and scope of the businesses engaged in the manufacture of cosmetic products and the risks to public health posed by cosmetic products.*

   We heard that existing national and international standards for cosmetic GMPs (e.g., ISO 22716:2007, NSF/ANSI 455-3-2022, FDA's 2013 Cosmetic GMP Draft Guidance) may provide

sufficient flexibility for all sizes and types of cosmetic facilities and products. Some speakers suggested using other FDA regulations (e.g., for human drugs) as a model for GMPs for cosmetic products in which the same general requirements apply to all entities and details for specific sizes and types of entities is provided through FDA guidance.

Several speakers also suggested that FDA take into account that cosmetic products may pose lower risks to public health than other FDA-regulated products and that there are different risks for different types of cosmetic products. Many speakers suggested FDA consider flexibility for certain GMP requirements, particularly for smaller businesses.

3. *Describe what constitutes simplified good manufacturing practices requirements for cosmetic products for smaller businesses to ensure regulations do not impose undue economic hardship.*

   We heard that smaller businesses may need additional flexibility for certain GMP requirements, such as for personnel, manufacturing space, sampling and testing of materials or products, or recordkeeping. Several speakers noted the importance of clear requirements that are easy to understand for smaller businesses. Some speakers also requested that FDA exempt smaller businesses from all GMP requirements.

   Several speakers also suggested that a single set of GMP requirements for all businesses, regardless of size, would be appropriate and consistent with existing national and international standards for cosmetic GMPs.

4. *Describe appropriate compliance times for good manufacturing practices regulations.*

   We heard suggested compliance times for GMP regulations ranging from 12 to 18 months after the effective date of the final GMP regulation. Several speakers noted that adopting existing national and international standards for cosmetic GMPs may facilitate faster compliance. Some speakers also requested longer compliance times for smaller businesses.

   Several speakers also suggested that FDA collaborate with and educate industry, particularly smaller businesses, before enforcing the GMP regulations. Suggestions included providing training or workshops on the GMP regulations, conducting site visits, and engaging with industry at conferences.

Topics Related to Economic Impact

5. *To what extent are manufacturers of cosmetic products already following a national or international standard for good manufacturing practices? For manufacturers of cosmetic products that are not currently following such a national or international standard, what would it cost to implement good manufacturing practices consistent with such a standard?*

   Many speakers stated they or other cosmetic product manufacturers are already following national or international standards for cosmetic GMPs (e.g., ISO 22716:2007, NSF/ANSI 455-3-2022, FDA's 2013 Cosmetic GMP Draft Guidance), including manufacturers ranging in size from

smaller to large businesses. Several speakers noted that GMP requirements would be costly for smaller businesses.

6. *Please provide reports or examples of adverse events or recalls associated with a cosmetic product that were linked to manufacturing practices. How would implementing good manufacturing practices impact the likelihood of a recall of cosmetics products? How would implementing good manufacturing practices impact the likelihood of consumers experiencing adverse events from the use of cosmetics products? How would these impacts differ by type of cosmetic product?*

   We heard examples of adverse events associated with cosmetic products, such as from contamination by microorganisms, asbestos, and other contaminants. Some speakers also noted issues with labeling and use of unapproved color additives in cosmetic products. Speakers suggested that GMP requirements, including production controls, testing of raw materials and products, and documentation, could help prevent these issues.