PUBLIC MEETING:

June 1, 2023

10:00 AM - 4:00 PM (Virtual)

FDA-2023-N-1466

Good Manufacturing Practices for Cosmetic Products Listening Session

Greeting & Housekeeping/Logistics

Dayle Lewis Cristinzio
Director, Stakeholder Engagement,
Office of External Affairs, FDA

Agenda (AM)

10:00 AM	**Greeting & Housekeeping/Logistics** Dayle Lewis Cristinzio, *Director, Stakeholder Engagement, Office of External Affairs, FDA*
10:05 AM	**Opening Remarks** Namandjé N. Bumpus, Ph.D., *Chief Scientist, FDA*
10:10 AM	**Brief Remarks on Cosmetic Good Manufacturing Practices** Linda M. Katz, M.D., M.P.H., *Director, Office of Cosmetics and Colors, FDA*
10:20 AM	**Open Public Comment** **Moderator:** Dayle Lewis Cristinzio, *Director, Stakeholder Engagement, Office of External Affairs, FDA*
11:30 AM	**BREAK**
11:35 AM	**Open Public Comment** **Moderator:** Dayle Lewis Cristinzio, *Director, Stakeholder Engagement, Office of External Affairs, FDA*

Agenda (PM)

1:00 PM	**BREAK**
1:15 PM	**Open Public Comment** **Moderator:** Dayle Lewis Cristinzio, *Director, Stakeholder Engagement, Office of External Affairs, FDA*
2:30 PM	**BREAK**
2:35 PM	**Open Public Comment** **Moderator:** Dayle Lewis Cristinzio, *Director, Stakeholder Engagement, Office of External Affairs, FDA*
3:55 PM	**Wrap-up and Next Steps** Linda M. Katz, M.D, M.P.H., *Director, Office of Cosmetics and Colors, FDA*
4:00 PM	**ADJOURN**

Opening Remarks

Namandjé N. Bumpus, Ph.D.
FDA's Chief Scientist, Office of the Chief Scientist, FDA

Cosmetic Good Manufacturing Practices

Linda M. Katz, M.D., M.P.H.
Director, Office of Cosmetics and Colors, CFSAN, FDA

Mission/Purpose

FDA's Mission

To Protect and Promote the Public Health

Purpose of Today's Meeting

The purpose of today's listening session is to consult cosmetics manufacturers, including smaller businesses and contract manufacturers, consumer organizations, and other experts to inform Agency efforts to develop regulations to establish good manufacturing practices for facilities that manufacture or process cosmetic products distributed in the United States.

Modernization of Cosmetics Regulation Act of 2022 (MoCRA)

MoCRA requires FDA to establish regulations on:

- Good Manufacturing Practices (GMP):
  - Consistent to extent practicable & appropriate with national & international standards
  - Take into account size and scope of business as well as public health risks of cosmetics
  - Provide flexibility

Deadlines:

- Proposed rule – by December 29, 2024 (statutory date)
- Final rule – by December 29, 2025 (statutory date)

Exemptions

- MoCRA exempts certain small businesses (a business with average gross annual sales for the previous three-year period of less than $1,000,000) from GMP.
- Such exemptions do not apply to the manufacturers or facilities that manufacture the following cosmetic products:
  - Products that regularly come into contact with mucus membrane of the eye under customary or usual conditions of use;
  - Products that are injected;
  - Products that are intended for internal use; and
  - Products that are intended to alter the appearance for more than 24 hrs. under customary or usual conditions of use and removal by the consumer is not part of such use.
- Exemptions also exist for certain products and facilities that are subject to requirements for drugs and devices.

Topics for Comment:
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.

Topics for Comment:
Topics Related to Good Manufacturing Practices

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.

Topics for Comment:
Topics Related to Good Manufacturing Practices

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

Topics for Comment:
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?

Topics for Comment:
Topics Related to Economic Impact

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 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?