



Ministry of Health
Department of Food and Drug Administration
Medical Device and Cosmetic Division



Amendment on Guideline of Cosmetic Notification

- According to the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme, requirement of product artwork during notification is optional but it is required for Product Information File (PIF) that is effective in December, 2024.
- All the applicants must follow the technical documents of ASEAN Cosmetic Directive (ACD).
- The company or person responsible for placing the cosmetic product in the market shall keep the Product Information File that are readily accessible to the regulatory authority.
- The certificate holder is responsible for quality, safety and performance of their products.
- If further information is needed, you can review the ACD documents as the followings :
 1. <https://esubmission.fda.gov.mm/user-guides/cosmetic-guides/TechnicalGuide/appendix-i.pdf>
 2. <https://esubmission.fda.gov.mm/user-guides/cosmetic-guides/TechnicalGuide/appendix-iii.pdf>
 3. <https://esubmission.fda.gov.mm/user-guides/cosmetic-guides/TechnicalGuide/appendix-ii.pdf>
 4. <https://esubmission.fda.gov.mm/user-guides/cosmetic-guides/TechnicalGuide/appendix.vi.pdf>
 5. <https://esubmission.fda.gov.mm/user-guides/cosmetic-guides/TechnicalGuide/ASEAN-Sunscreen-Labeling-Guideline.pdf>
 6. <https://esubmission.fda.gov.mm/user-guides/cosmetic-guides/TechnicalGuide/a-guide-manual-for-the-industry.pdf>
 7. <https://esubmission.fda.gov.mm/user-guides/cosmetic-guides/TechnicalGuide/guidelines-for-product-information-file.pdf>

8. <https://esubmission.fda.gov.mm/user-guides/cosmetic-guides/TechnicalGuide/ASEAN-Botanical-Safety-Assessment-Guidance.pdf>
9. <https://esubmission.fda.gov.mm/user-guides/cosmetic-guides/TechnicalGuide/QA-on-Specific-Provisions-of-the-ASEAN-Cosmetic-Directive-ACD.pdf>
10. https://esubmission.fda.gov.mm/user-guides/cosmetic-guides/TechnicalGuide/ANNEXES%20OF%20THE%20ASEAN%20COSMETIC%20DIRECTIVE_update.pdf



11. Guidance-Format-of-the-Safety-Assessme