



Regulations on Supervision and Administration of Enterprises in Implementing Entity Responsibility for Cosmetic Quality and Safety (Draft for Comments)

企业落实化妆品质量安全主体责任监督管理规定
(征求意见稿)

National Medical Products Administration

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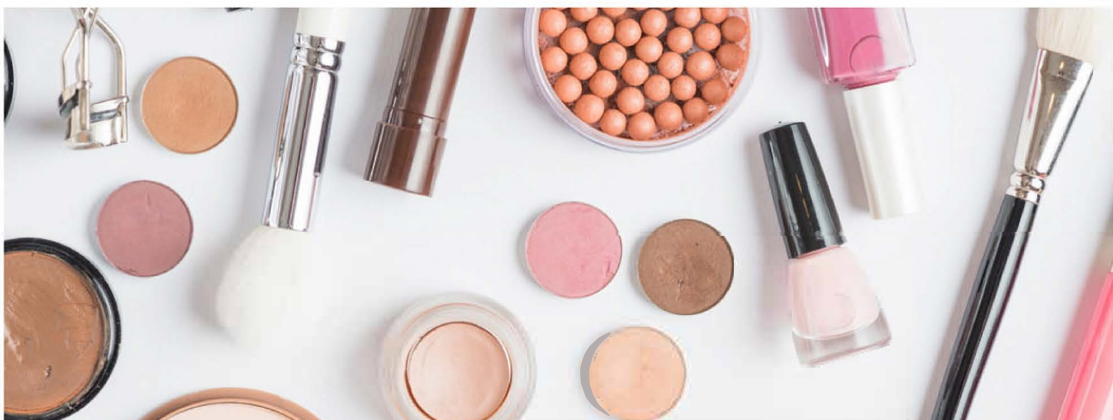
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Attachment 1

Regulations on Supervision and Administration of Enterprises in Implementing Entity Responsibility for Cosmetic Quality and Safety (Draft for Comments)

Chapter I General Provisions

Article 1 Basis and Purpose For the purpose of supervising and urging enterprises to implement the entity responsibility for cosmetic quality and safety, strengthening enterprises' awareness of the responsibility for quality and safety, standardizing the management of cosmetic quality and safety, and ensuring the quality and safety of cosmetics, these Regulations are hereby formulated in accordance with the *Cosmetic Supervision and Administration Regulation (CSAR)*, *Supervision and Administration Measures on Cosmetics Manufacture and Operation*, *Good Manufacturing Practices for Cosmetics* and other laws and regulations.

Article 2 Scope of Application These Regulations apply to cosmetics registrants, notifiers and entrusted production enterprises (hereinafter collectively referred to as "enterprises") in terms of the acts of implementing the responsibility for cosmetic quality and safety according to laws within the territory of the People's Republic of China, as well as the supervision and administration over them.

Article 3 Responsibility Entity Cosmetics registrants and notifiers shall be responsible for the quality and safety, and the efficacy claims of cosmetics, and shall manage the quality and safety of their registered or notified cosmetics during the whole process from R&D, production to operation.

Where a cosmetics registrant or notifier entrusts the production of cosmetics, he/she shall supervise the whole production process, and be responsible for the quality and safety of the cosmetics entrusted for production. The entrusted production enterprise shall be responsible for the production activities, and accept the supervision of the entrusting party.

Article 4 Quality and Safety Responsibility System Enterprises shall establish a responsibility system for cosmetic quality and safety, defining the responsibilities of the cosmetic quality and safety related posts. The personnel in each post shall perform the corresponding cosmetic quality and safety obligations level by level according to the post

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附件 1

企业落实化妆品质量安全主体责任 监督管理规定 (征求意见稿)

第一章 总 则

第一条(依据和目的) 为了督促企业落实化妆品质量安全主体责任,强化企业质量安全责任意识,规范化妆品质量安全管理行为,保证化妆品质量安全,根据《化妆品监督管理条例》《化妆品生产经营监督管理办法》《化妆品生产质量管理规范》等法律法规,制定本规定。

第二条(适用范围) 在中华人民共和国境内化妆品注册人、备案人、受托生产企业(以下统称“企业”)依法落实化妆品质量安全责任的行为及其监督管理,适用本规定。

第三条(责任主体) 化妆品注册人、备案人对化妆品的质量安全和功效宣称负责,对其注册或者备案的化妆品从研发、生产、经营全过程质量安全进行管理。

化妆品注册人、备案人委托生产化妆品的,应当对生产活动全过程进行监督,对委托生产的化妆品的质量安全负责。受托生产企业对生产活动负责,接受委托方的监督。

第四条(质量安全责任制) 企业应当建立化妆品质量安全责任制,明确化妆品质量安全相关岗位的职责,各岗位人员应当按照岗位职责要求,逐级履行相应的化妆品质量安全义务,落实化妆品质量安全主体责任。

第二章 质量安全关键岗位要求

第五条(主体责任构架) 企业法定代表人(或者主要负责人,下同)对化妆品质量安全工作全面负责。

企业应当设质量安全负责人。质量安全负责人应当按照质量安全责任制的要求,协助法定代表人组织领导企业质量安全管理相关人员依法履行质量安全管理职责。

第六条(法定代表人委托履职) 企业法定代表人根据企业质量管理体系运行需要,可以委托本企业其他人员代为履行化妆品质量安全全面管理工作。法定代表人应当与被委托人签订授权委托书,明确被委托人应当履行的质量管理职责并授予相应的权限。被



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