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Administrative Measures on Cosmetics Inspection (Draft for Comments)

《化妆品检查管理办法（征求意见稿）》

National Medical Products Administration

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Translated by ChemLinked

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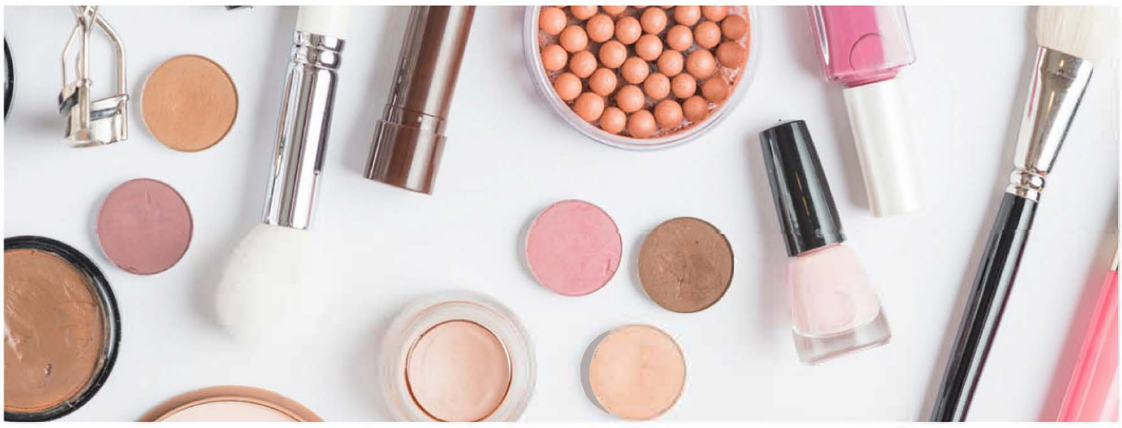

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Attachment 1

Administrative Measures on Cosmetic Inspection

(Draft for Comments)

Chapter I General Provisions

Article 1 Legislative Purpose In order to standardize the inspection of cosmetic products, this *Measures* is hereby formulated in accordance with the *Cosmetic Supervision and Administration Regulations* (CSAR), *Administrative Measures on Cosmetic Registration and Notification*, *Supervision and Administration Measures on Cosmetic Production and Operation*, and other relevant regulations and rules.

Article 2 Scope of Application This *Measures* shall apply to medical products administration departments for conducting inspection on the compliance of cosmetic producers and operators within the territory of the People's Republic of China with laws and regulations, mandatory national standards, technical specifications, and technical requirements specified in cosmetic registration or notification dossiers.

Article 3 Basic Principles Cosmetic inspection work shall follow the principles of being law-based and impartial, scientific and standard, and of risk management.

Article 4 Assignment of Responsibilities The National Medical Products Administration (NMPA) shall be responsible for the national cosmetic inspection and management work.

Medical products administration departments at or above the county level shall be responsible for the cosmetic inspection and management in their respective administrative regions.

Article 5 Obligation to Cooperate with Inspection When medical products administration departments conduct inspection in accordance with the law, the inspected units and individuals such as cosmetic producers and operators (hereinafter collectively referred to as the "inspected objects") shall accept the inspection, actively cooperate, and provide true, complete, and accurate records, bills, data, information, *etc.*, and shall not refuse, evade, delay, or hinder the

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附件 1

化妆品检查管理办法
（征求意见稿）

第一章　总　则

第一条【立法目的】　为规范化妆品检查工作，根据《化妆品监督管理条例》《化妆品注册备案管理办法》《化妆品生产经营监督管理办法》等有关法规、规章，制定本办法。

第二条【适用范围】　负责药品监督管理的部门对在中华人民共和国境内的化妆品生产经营者遵守法律法规、强制性国家标准、技术规范和化妆品注册或者备案资料载明的技术要求等情况开展检查，适用本办法。

第三条【基本原则】　化妆品检查工作应当遵循依法公正、科学规范、风险管理的原则。

第四条【职责分工】　国家药品监督管理局负责全国化妆品检查管理工作。

县级以上负责药品监督管理的部门负责本行政区域的化妆品检查管理工作。

第五条【检查配合义务】　负责药品监督管理的部门依法检查时，化妆品生产经营者等被检查单位和个人（以下统称“被检查对象”）应当接受检查，积极配合，并提供真实、完整、准确的记录、票据、数据、信息等，不得拒绝、逃避、拖延或者阻碍检查。

第六条【检查机构】　负责药品监督管理的部门和依法设置或者指定的检查机构（以下简称“检查机构”）依据法律、法规、规章等开展检查工作。负责药品监督管理的部门设立或者指定的化妆品检验、不良反应监测等其他机构为化妆品检查机构提供技术支撑。

国家级检查机构负责组织开展国家药品监督管理局布置的化妆品生产环节等检查，并协助国家药品监督管理局对各省、自治区、直辖市药品监督管理部门的化妆品检查工作进行指导。

鼓励检查机构建立质量管理体系，不断完善和持续改进化妆品检查工作，保证检查质量。

第七条【检查分类】　根据检查的性质和目的，化妆品检查分为许可检查、常规检查、有因检查和其他检查。

（一）许可检查是指负责药品监督管理的部门在开展化妆品生产许可过程中，对申请人

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