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Working Rules for Management of Cosmetic Supplementary Testing Methods

化妆品补充检验方法管理工作规程

National Medical Products Administration

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Translated by ChemLinked

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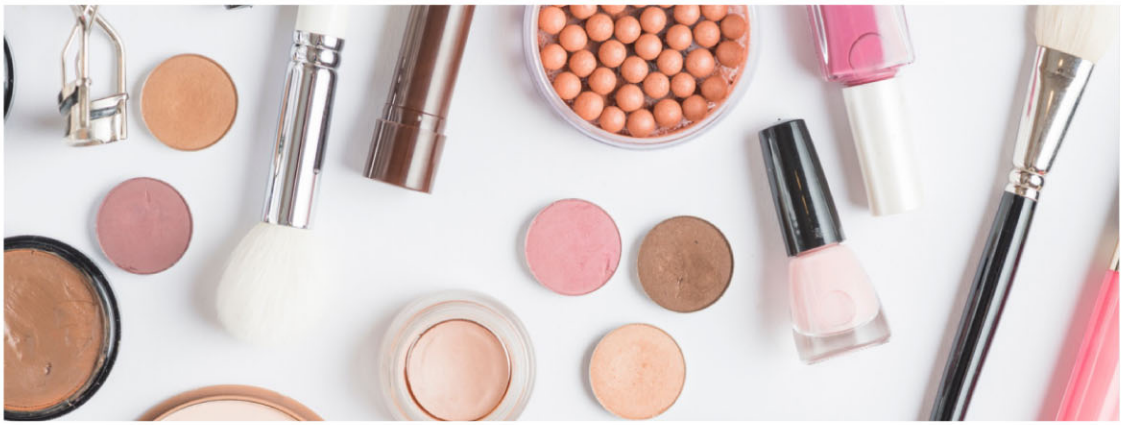

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Working Rules for Management of Cosmetics Supplementary Testing Methods

Chapter I General Provisions

Article 1 For the purpose of normalizing the management of cosmetics supplementary testing methods, the Rules are hereby formulated based on the *Cosmetic Supervision and Administration Regulations*.

Article 2 Where cosmetics that may be adulterated or produced with ingredients that are prohibited in production of cosmetics cannot be tested in accordance with the testing items and testing methods prescribed in national cosmetics standards and technical specifications, the National Medical Products Administration (NMPA) can develop supplementary testing items and testing methods (hereinafter referred to as the "cosmetics supplementary testing methods") for sampling testing, investigation and handling of quality and safety cases, and investigation and disposal of adverse reactions of cosmetics, and the testing results can serve as a basis for law enforcement.

Cosmetics supplementary testing methods applies to not only the testing of cosmetics produced after the release date of the methods, but also the testing of cosmetics produced before the release date of the methods.

Article 3 The NMPA shall be responsible for the management of cosmetics supplementary testing methods, including the organization of project establishment, drafting and validation of cosmetics supplementary testing methods, and the review, approval and release of such methods.

Article 4 The management of cosmetics supplementary testing methods shall follow the principles of regulatory needs, scientificity and practicability, normalization and high efficiency, and justice and fairness.

Article 5 The NMPA shall organize the formation of an Expert Committee on Cosmetics Supplementary Testing Methods (hereinafter referred to as the "Expert Committee"), which shall be mainly responsible for giving review comments on project establishment application of cosmetics supplementary testing methods and method drafts. An Expert Group and a Secretariat shall be set up under the Expert Committee.

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化妆品补充检验方法管理工作规程

第一章 总 则

第一条 为规范化妆品补充检验方法管理工作，依据《化妆品监督管理条例》，制定本规程。

第二条 对可能掺杂掺假或者使用禁止用于化妆品生产的原料生产的化妆品，按照化妆品国家标准和技术规范规定的检验项目和检验方法无法检验的，国家药品监督管理局可以制定补充检验项目和检验方法（以下简称化妆品补充检验方法），用于化妆品的抽样检验、质量安全案件调查处理和不良反应调查处置，其检验结果可以作为执法依据。

化妆品补充检验方法不仅适用于方法发布日期之后生产的化妆品的检验，同样适用于方法发布日期之前生产的化妆品的检验。

第三条 国家药品监督管理局负责化妆品补充检验方法的管理工作，包括化妆品补充检验方法立项、起草、验证的组织工作，以及方法的审查、批准和发布等。

第四条 化妆品补充检验方法的管理应当遵循监管需要、科学实用、规范高效、公平公正的原则。

第五条 国家药品监督管理局组织成立化妆品补充检验方法专家委员会（以下简称专家委员会），主要负责对化妆品补充检验方法立项申报和方法草案提出审查意见。专家委员会设专家组和秘书处。

专家组由药品监督管理部门、化妆品检验机构和其他化妆品相关专业技术机构等领域人员组成，主要负责对化妆品补充检验方法立项申报和方法草案进行实质性审查。

秘书处设在中国食品药品检定研究院，主要负责对化妆品补充检验方法立项申报和方法草案进行形式审查，组织专家组会议审查和函审、报送方法草案等，并承担化妆品补充检验方法立项、起草、验证、审查、报送的相关咨询工作。

第六条 制定化妆品补充检验方法，应当注重方法的科学性、通用性和时效性，并可以借鉴国际上广泛认可的化妆品检验方法或者有关部门已经发布的化妆品检验方法。

国家鼓励吸纳科研院所、大专院校或者社会力量举办的相关领域研究机构的技术能力，运用新技术研究开发化妆品补充检验方法，提高方法准确性和检验效率。

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