



Technical Guidance for Studying and Drafting Cosmetics Supplementary Testing Methods

化妆品补充检验方法研究起草技术指南

National Medical Products Administration

Release Date: Apr 28, 2021

Translated by ChemLinked

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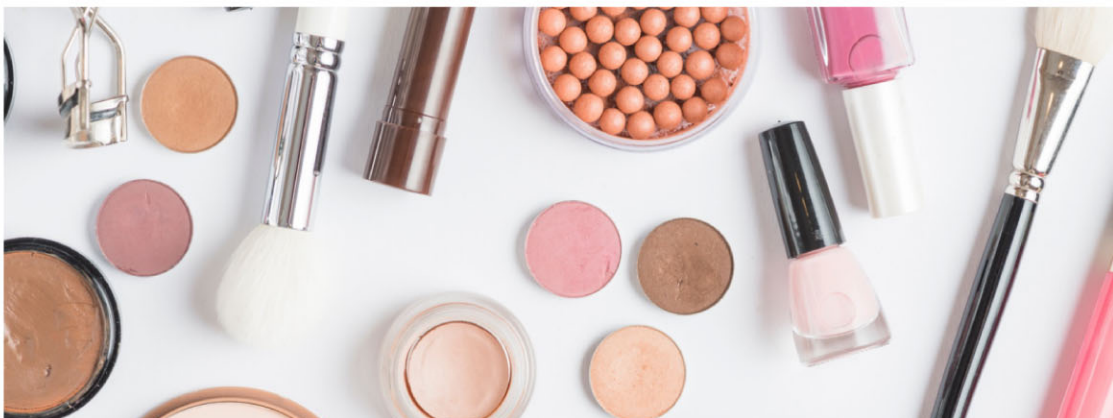
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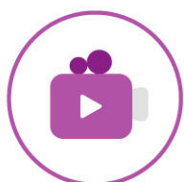


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Technical Guidance for Studying and Drafting Cosmetics Supplementary Testing Methods

For the purpose of normalizing the study and development of cosmetics supplementary testing methods and ensuring the scientificity, universality and timeliness of cosmetics supplementary testing methods, the Guidance is hereby formulated based on the *Cosmetic Supervision and Administration Regulations* and the *Working Rules for Management of Cosmetic Supplementary Testing Methods*.

I. Main Study and Development Directions

- (I) To identify cosmetics that may be adulterated;
- (II) To identify cosmetics that may be produced by using the prohibited ingredients for cosmetic production;
- (III) Other study and development directions that comply with the provisions of *Working Rules for Management of Cosmetic Supplementary Testing Methods*, which require establishment of methods.

II. Project Establishment Application

Application units shall submit a project proposal in accordance with the provisions of the *Working Rules for Management of Cosmetic Supplementary Testing Methods*, which shall include the following contents:

- (I) The importance of relevant testing items on the safety supervision of cosmetics, the purpose and the basis for project establishment, and the focus shall be laid on the actual problems to be solved, the relationship of the methods established and the cosmetics supervision, and the significance;
- (II) The current situation of domestic and international study and the foundation of preliminary work;
- (III) The specific technical route of establishing testing methods and study programme.

III. Method Study and Development and Validation

Drafting units of cosmetics supplementary testing methods shall carry out method study and development in accordance with the following requirements:

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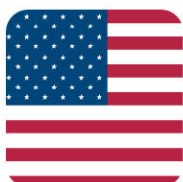
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- + Functional cosmetic registration
- + Ingredients registration by ICID



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- + Cosmetics notification
- + Ingredients analysis and full ingredient list translation
- + Cosmetic test service
- + Label & advertisement review



- + Responsible Person (RP) service in the EU & UK
- + Cosmetic Product Notification Portal (CPNP)
- + Cosmetic Product Safety Report (CPSR)
- + Preparation of Product Information File (PIF)



- + Cosmetic formula and label compliance review
- + FDA Voluntary Cosmetic Registration Program (VCRP)
- + California Safe Cosmetics Program (CSCP)
- + Toxicological Risk Assessment (TRA)
- + INCI application

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化妆品补充检验方法研究起草技术指南

为规范化妆品补充检验方法研制工作，确保化妆品补充检验方法的科学性、通用性和时效性，依据《化妆品监督管理条例》和《化妆品补充检验方法管理工作规程》，制定本指南。

一、主要研制方向

- (一) 识别可能掺杂掺假的化妆品；
- (二) 识别可能使用禁止用于化妆品生产的原料生产的化妆品；
- (三) 符合《化妆品补充检验方法管理工作规程》规定的其他需要建立方法的研制方向。

二、立项申报

申报单位按照《化妆品补充检验方法管理工作规程》的规定提交立项建议，立项建议需提供如下内容：

- (一) 相关检验项目对化妆品安全监管的重要性、目的和立项依据，重点说明拟解决的实际问题、建立的方法与化妆品监管的关系和意义；
- (二) 国内外研究的现状和前期工作基础；
- (三) 检验方法建立的具体技术路线和研究方案。

三、方法研制和验证

化妆品补充检验方法起草单位应当按照以下要求开展方法研制工作：

- (一) 在深入调查研究、充分论证技术指标的基础上进行研制，并充分征求技术机构、监管部门等的意见，保证方法的科学性、通用性和时效性。
- (二) 起草方法草案文本时，应当参考化妆品补充检验方法编写规则，包括适用范围、方法原理、试剂仪器、分析步骤、计算结果等，同时还应当编制起草说明，包括相关背景、研制过程、各项技术参数的依据、实验室内和实验室间验证情况和数据等。
- (三) 根据所起草方法的技术特点，原则上应当选择不少于 3 家化妆品补充检验方法验证单位进行验证，验证单位应当出具验证报告。起草单位应当根据验证报告对方法进行修改完善。



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