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Measures for the Management of Cosmetic Sampling Testing

化妆品抽样检验管理办法

National Medical Products Administration

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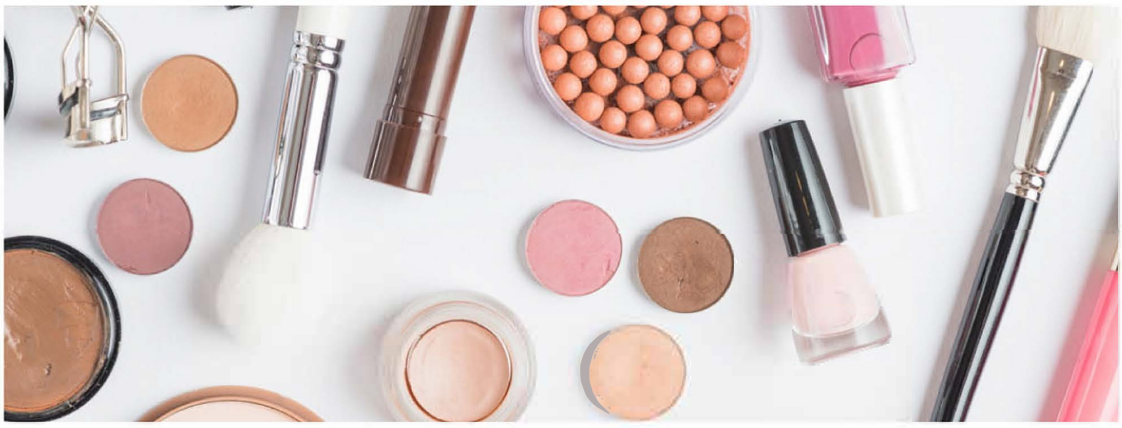

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Measures for the Management of Cosmetics Sampling Testing

Chapter I General Provisions

Article 1 In order to strengthen the supervision and administration and standardize the sampling testing of cosmetics, these measures are hereby formulated in accordance with the *Cosmetic Supervision and Administration Regulations*, the *Supervision and Administration Measures on Cosmetics Manufacture and Operation* and other laws and regulations.

Article 2 Medical products administration departments shall comply with these Measures when organizing and implementing cosmetics sampling testing within the territory of the People's Republic of China.

Article 3 Medical products administration departments shall follow the principles of science, standardization, legality and impartiality in organization and implementation of the cosmetics sampling testing work, and strengthen the whole process administration of sampling, testing, objection review and re-testing, verification and disposal, and information disclosure.

Article 4 The National Medical Products Administration (NMPA) shall organize and carry out national cosmetics sampling testing every year.

The medical products administration departments of provinces, autonomous regions and municipalities directly under the Central Government shall organize and carry out cosmetics sampling testing in their respective administrative regions every year, and undertake the task of national cosmetics sampling testing according to the requirements of the NMPA.

The medical products administration departments at the municipality level with districts and county level shall organize and carry out cosmetics sampling testing in their respective administrative regions according to work needs, and undertake the task of cosmetics sampling testing according to the requirements of medical products administration departments at the next higher level.

Article 5 Cosmetics manufacturers and operators shall accept the cosmetics sampling testing organized and implemented by medical products administration departments according to law, and shall not interfere with, hinder or refuse the sampling testing work, and shall not provide false information.

Article 6 For cosmetics sampling, the fee of taking samples shall be paid. The fee required for sampling testing shall be included in the government budget according to relevant national provisions.

Article 7 The NMPA shall be responsible for establishing the national cosmetics sampling testing information system and strengthening the information construction of cosmetics sampling testing.

Chapter II Plan Formulation

Article 8 Medical products administration departments that organize sampling testing (hereinafter referred to as the “department organizing sampling testing”) shall formulate the sampling testing plan.

The NMPA shall formulate the annual national cosmetics sampling testing plan every year. The medical products administration departments of provinces, autonomous regions and municipalities directly under the Central Government shall formulate the implementation plan for their respective administrative regions according to the annual national cosmetics sampling testing plan.

The medical products administration departments of provinces, autonomous regions and municipalities directly under the Central Government shall formulate the annual cosmetics sampling testing plan for their respective administrative regions every year. The provincial-level cosmetics sampling testing plan shall be linked up with the national cosmetics sampling testing plan each other, with each having its own emphasis, so that the sampling coverage will be expanded, and repeated sampling will be avoided.

The medical products administration departments at the municipality level with districts and county level shall formulate the cosmetics sampling testing plan for their respective

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附件

化妆品抽样检验管理办法

第一章　总　则

第一条　为了加强化妆品监督管理，规范化妆品抽样检验工作，根据《化妆品监督管理条例》《化妆品生产经营监督管理办法》等法规、规章，制定本办法。

第二条　在中华人民共和国境内，负责药品监督管理的部门组织实施化妆品抽样检验工作，应当遵守本办法。

第三条　负责药品监督管理的部门应当遵循科学、规范、合法、公正的原则，组织实施化妆品抽样检验工作，加强对抽样、检验、异议审查和复检、核查处置及信息公开的全过程管理。

第四条　国家药品监督管理局每年组织开展国家化妆品抽样检验工作。

省、自治区、直辖市药品监督管理部门每年组织开展本行政区域内的化妆品抽样检验工作，并按照国家药品监督管理局的要求，承担国家化妆品抽样检验任务。

设区的市级、县级负责药品监督管理的部门根据工作需要，组织开展本行政区域内的化妆品抽样检验工作，并按照上级负责药品监督管理的部门的要求，承担化妆品抽样检验任务。

第五条　化妆品生产经营者应当依法接受负责药品监督管理的部门组织实施的化妆品抽样检验，不得干扰、阻碍或者拒绝抽样检验工作，不得提供虚假信息。

第六条　化妆品抽样应当支付抽取样品的费用。抽样检验所需费用按照国家有关规定列入政府预算。

第七条　国家药品监督管理局负责建立国家化妆品抽样检验信息系统，加强化妆品抽样检验信息化建设。

第二章　计划制定

第八条　组织抽样检验的负责药品监督管理的部门（以下简称“组织抽检部门”）应当制定抽样检验计划。

国家药品监督管理局应当每年制定年度国家化妆品抽样检验计划。省、自治区、直辖市药品监督管理部门应当按照年度国家化妆品抽样检验计划，制定本行政区域的实施方案。

省、自治区、直辖市药品监督管理部门应当每年制定本行政区域年度化妆品抽样检验计划。省级化妆品抽样检验计划应当与国家化妆品抽样检验计划相互衔接，各有侧重，扩大抽样覆盖面，避免重复抽样。

设区的市级、县级负责药品监督管理的部门根据工作需要，制定本行政区域化妆品抽样检验计划。

第九条　化妆品抽样检验计划应当包括下列内容：

（一）抽样的品类；

（二）抽样区域、环节、场所、数量、时限等抽样工作要求；

（三）检验项目、检验方法、判定依据、检验时限等检验工作要求；

（四）检验报告的报送方式和时限；

（五）对检验结论为不符合规定产品的核查处置要求；

（六）其他工作要求。

第十条　化妆品抽样检验应当重点关注下列产品：

（一）儿童化妆品和特殊化妆品；

（二）使用新原料的化妆品；

（三）监督检查、案件查办、不良反应监测、安全风险监测、投诉举报、舆情监测等监管工作中发现问题较多的；

（四）既往抽样检验不合格率较高的；

（五）流通范围广、使用频次高的；

（六）其他安全风险较高的产品。

第三章　抽　样

第十一条　抽样工作应当坚持问题导向、广泛覆盖、监督检查与抽样检验相结合的原则。

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