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Measures for the Management of Cosmetic Adverse Reaction Monitoring

化妆品不良反应监测管理办法

National Medical Products Administration

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Translated by ChemLinked

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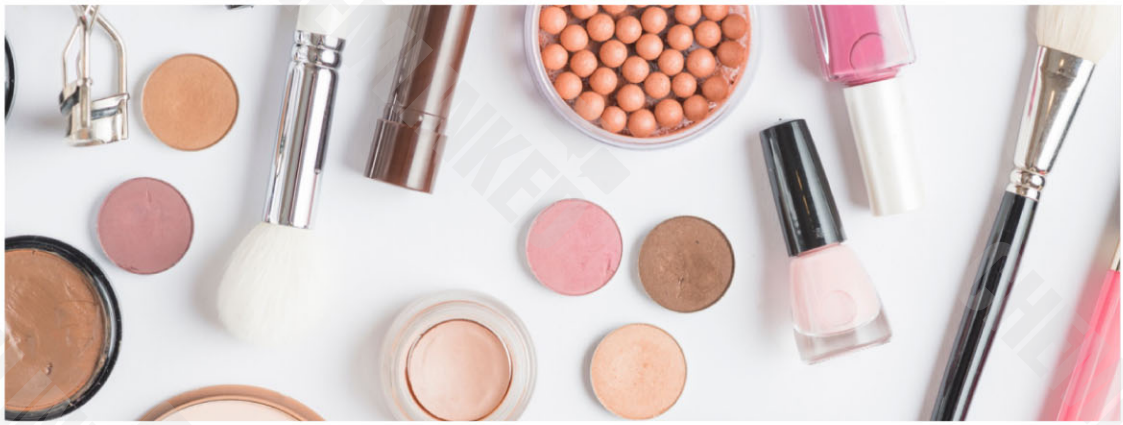

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Attachment

Measures for the Management of Cosmetic Adverse Reaction Monitoring

Chapter I General Provisions

Article 1 In order to strengthen the monitoring of cosmetic adverse reactions, timely and effectively control the safety risks of cosmetics, and protect the health of consumers, these Measures are hereby formulated in accordance with the *Cosmetic Supervision and Administration Regulations* (CSAR), *Supervision and Administration Measures on Cosmetics Manufacture and Operation* and other regulations and rules.

Article 2 These Measures shall apply to the implementation of cosmetic adverse reaction monitoring and its supervision and administration within the territory of the People's Republic of China.

Article 3 The National Medical Products Administration (NMPA) shall be responsible for the administration of cosmetic adverse reaction monitoring nationwide. The medical products administration departments of the local people's governments at or above the county level shall be responsible for the administration of cosmetic adverse reaction monitoring in their respective administrative regions.

The medical products administration departments of the local people's governments at or above the county level shall define the cosmetic adverse reaction monitoring institutions to be responsible for the technical work of cosmetic adverse reaction monitoring within their respective administrative regions.

Article 4 Cosmetic registrants and notifiers shall establish a cosmetic adverse reaction monitoring and evaluation system, actively collect adverse reactions of their marketed cosmetics, timely carry out analysis and evaluation, and in accordance with the provisions herein, report to the cosmetic adverse reaction monitoring institutions, and implement main responsibility for cosmetic quality and safety. Entrusted production enterprises, cosmetics operators and medical institutions shall report any observed adverse reaction that may be related to the use of cosmetics to the cosmetic adverse reaction monitoring institutions in accordance with the provisions herein.

Article 5 Other units and individuals are encouraged by the State to report adverse

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附件

化妆品不良反应监测管理办法

第一章　总　则

第一条　为加强化妆品不良反应监测工作，及时有效控制化妆品安全风险，保障消费者健康，依据《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开展化妆品不良反应监测及其监督管理，适用本办法。

第三条　国家药品监督管理局负责全国化妆品不良反应监测管理工作。县级以上地方人民政府负责药品监督管理的部门负责本行政区域的化妆品不良反应监测管理工作。

县级以上地方人民政府负责药品监督管理的部门应当明确化妆品不良反应监测机构，负责本行政区域的化妆品不良反应监测技术工作。

第四条　化妆品注册人、备案人应当建立化妆品不良反应监测和评价体系，主动收集其上市销售化妆品的不良反应，及时开展分析评价，并按照本办法规定向化妆品不良反应监测机构报告，落实化妆品质量安全主体责任。受托生产企业、化妆品经营者和医疗机构发现可能与使用化妆品有关的不良反应，应当按照本办法规定向化妆品不良反应监测机构报告。

第五条　国家鼓励其他单位和个人向化妆品不良反应监测机构或者负责药品监督管理的部门报告可能与使用化妆品有关的不良反应，充分发挥社会监督作用，促进化妆品安全社会共治。

第六条　国家药品监督管理局负责建立国家化妆品不良反应监测信息系统，加强化妆品不良反应监测信息化建设。

第二章　职责与义务

第七条　国家药品监督管理局负责全国化妆品不良反应监测管理工作，履行以下主要职责：

（一）建立并完善全国化妆品不良反应监测管理体系，组织制定化妆品不良反应监

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