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Measures for the Management of Cosmetic Adverse Reaction Monitoring (Second Draft for Comments)

化妆品不良反应监测管理办法(征求意见稿)

National Medical Products Administration

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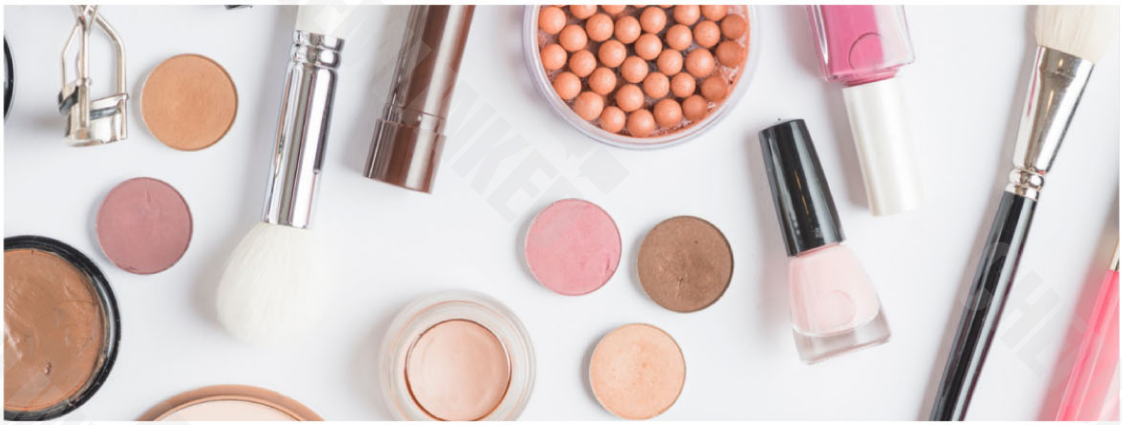

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Measures for the Management of Cosmetic Adverse Reaction Monitoring

(Second Draft for Comments)

Chapter I General Provisions

Article 1 Legislative Purpose 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 Scope of Application These Measures shall apply to the cosmetic adverse reaction monitoring and its supervision and administration within the territory of the People's Republic of China.

Article 3 Division of Responsibilities 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 at all levels shall establish and improve the cosmetic adverse reaction monitoring institutions, and be responsible for the technical work of cosmetic adverse reaction monitoring within their respective administrative regions.

Article 4 Main Responsibility Cosmetic registrants and notifiers shall establish a cosmetic adverse reaction monitoring and evaluation system, actively collect adverse reactions of their marketed cosmetics, carry out evaluations in a timely manner, 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 adverse reactions that may be related to the use of cosmetics to the cosmetic

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（征求意见稿）

第一章　总　则

第一条【立法目的】　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【适用范围】　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【职责分工】　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。

各级负责药品监督管理的部门应当建立健全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【主体责任】　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，及时开展评价，并按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，应当按本办法规定向化妆品不良反应监测机构报告。

第五条【社会共治】　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【监测系统】　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网络和数据库建设。

第二章　职责与义务

第七条【国家局职责】　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，并履行以下主要职责：

（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测管理规定和政策，并监督实施；

（二）组织调查、处理可能引发较大社会影响的化妆品不良反应，依法采取控制措施；

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