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Measures for the Management of Cosmetic Adverse Reaction Monitoring (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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Translated by ChemLinked

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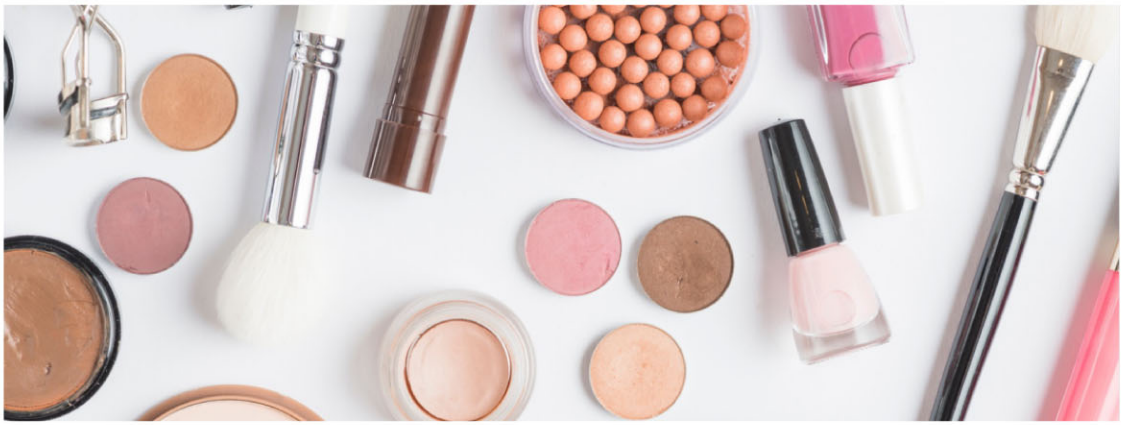

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(Draft for Comments)

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) 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 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 local medical products administration departments 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 of Enterprise The state establishes and implements a cosmetic adverse reaction monitoring system. Cosmetic registrants and notifiers shall monitor the adverse reactions of their marketed cosmetics, carry out evaluations in a timely manner, and report to the cosmetic adverse reaction monitoring institutions in accordance with the provisions herein. The domestic enterprise legal persons (hereinafter referred to as the "domestic responsible persons") designated by overseas registrants and notifiers shall assist the cosmetics registrant and notifiers to carry out the cosmetic adverse reaction monitoring and perform the obligations of monitoring the cosmetic adverse reactions. Entrusted production enterprises, cosmetics operators and medical

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