CHEMLINKED
by REACH24H Consulting Group

Administrative Measures on Safety Risk Monitoring of Cosmetics (Draft for Comments)

化妆品安全风险监测管理办法(征求意见稿)

National Medical Products Administration

Release Date: Sep. 14, 2024
Implementation Date: /

Translated by ChemLinked

Disclaimer

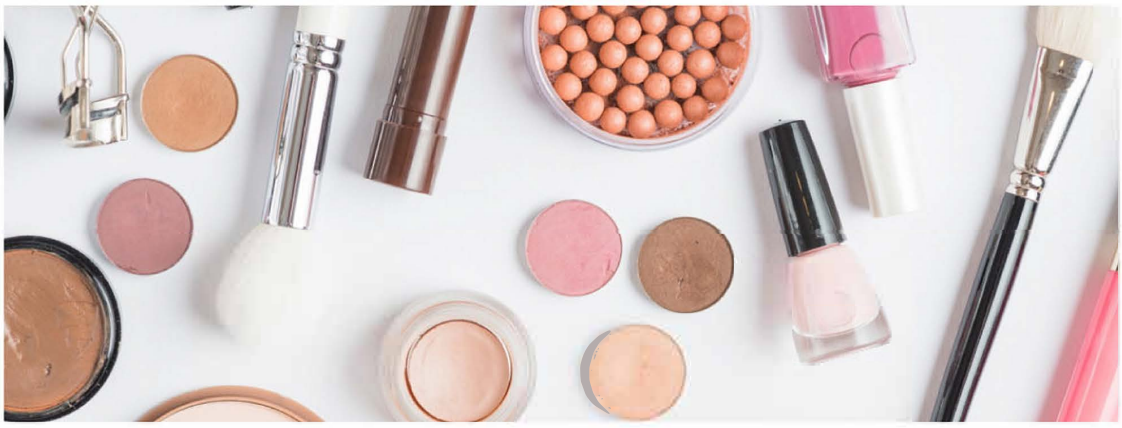
ChemLinked provides translation services to assist clients in understanding the content of regulatory documents. We strive for the accuracy and reliability of our translations, but we do not warrant the accuracy, completeness, or suitability of the translated content.

Clients are responsible for the risks inherent in utilizing our translation services and should consult with professional legal advisors as required. ChemLinked disclaims any liability for any losses or damages arising from the use of our translation services.

Nondisclosure:

You may not disclose this document to anyone else without the written permission of ChemLinked.

For further clarification and questions, you can read our Privacy Policies or contact us at contact@chemlinked.com



You can now catch up with the latest updates of China CSAR on ChemLinked:

Stay tuned for more translations:
We will provide English translations of CSAR and supporting rules.

Watch our webinars:
Interpretation of China's Cosmetic Supervision and Administration Regulation

Check out the breaking news:
China Finalises the Long-Awaited Cosmetic Supervision and Administration Regulation

Visit the featured page for more information:
Featured — China Cosmetic Regulatory Reform Tracking

— CSAR —

Attachment 1

Administrative Measures on Safety Risk Monitoring of Cosmetics

(Draft for Comments)

Chapter 1 General Provisions

Article 1 Legislative Purpose This *Measures* is formulated in accordance with the *Cosmetic Supervision and Administration Regulations*, *Supervision and Administration Measures on Cosmetic Production and Operation*, and other regulations and rules for the purpose of strengthening the supervision and administration and standardizing the safety risk monitoring of cosmetics (hereinafter referred to as "risk monitoring").

Article 2 Application Scope The medical products administration departments shall comply with this *Measures* when carrying out risk monitoring work within the territory of the People's Republic of China.

Article 3 Definition The "risk monitoring" referred to in this *Measures* means the activities of the medical products administration departments to monitor, analyze, research, judge, and effectively dispose of the risk factors that may affect the quality and safety of cosmetics through inspection, testing and other means. The purpose thereof is to discover and prevent and control safety risks in cosmetics, providing scientific basis for developing quality and safety risk control measures and standards for cosmetics, conducting cosmetic sampling and testing, communicating and warning about cosmetic safety risks.

Article 4 Division of Responsibilities The National Medical Products Administration (NMPA) shall be responsible for the risk monitoring and administration work nationwide and organizing the implementation of national risk monitoring.

The medical products administration departments of provinces, autonomous regions, and municipalities directly under the Central Government shall organize and carry out risk monitoring within their respective administrative regions according to work needs. They

Make Sure Your Products Entering Global Market with Compliance

What we can do for you?

+ Responsible person (RP) service in China
+ Cosmetic formula and label compliance review
+ Product registration and notification
+ New cosmetic ingredient (NCI) registration and notificaion
+ Ingredient safety information submission
+ Cosmetic efficacy evaluation

+ Cosmetic formula and label compliance review
+ EDI Notification
+ Cosmetic QC test service
+ Functional cosmetic registration
+ Ingredients registration by ICID

+ Marketing license application
+ 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

What makes us unique?

- ☑ Connect with officials and associations
- ☑ Flexible consulting service packages
- ☑ Team of qualified toxicology and regulatory experts

CONTACT US | ☎ +86 571 8609 4444 ✉ cosmetic@chemlinked.com

附件 1

化妆品安全风险监测管理办法
（征求意见稿）

第一章　总　则

第一条【立法目的】　为了加强化妆品监督管理，规范化妆品安全风险监测（以下简称“风险监测”）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【适用范围】　在中华人民共和国境内，负责药品监督管理的部门开展风险监测工作，应当遵守本办法。

第三条【定义】　本办法所称风险监测，是指负责药品监督管理的部门通过检验检测等手段对可能影响化妆品质量安全的风险因素进行监测、分析研判和有效处置的活动。其目的是发现和防控化妆品安全风险，为制定化妆品质量安全风险控制措施和标准、开展化妆品抽样检验、化妆品安全风险交流和预警提供科学依据。

第四条【职责分工】　国家药品监督管理局负责全国风险监测管理工作，组织开展国家风险监测。

省、自治区、直辖市药品监督管理部门根据工作需要，组织开展本行政区域内的风险监测；按照国家药品监督管理局的要求，承担国家风险监测任务。

设区的市级、县级药品监督管理部门根据工作需要，组织开展本行政区域内的风险监测；按照上级药品监督管理部门的要求，承担风险监测任务。

第五条【信息系统】　国家药品监督管理局负责建立国家风险监测信息系统，加强风险监测信息化建设。

第六条【信息保密】　风险监测工作中的监测数据及相关信息应当予以保密。

第二章　计划制定

第七条【基本原则】　国家风险监测计划应当统筹兼顾发现化妆品潜在风险和为标准制修订提供科学依据，省级及以下药品监督管理部门的风险监测计划主要聚焦发现化妆品潜在风险。

CHEMLINKED
by REACH24H Consulting Group

SUBSCRIBE TO CHEMLINKED NOW

REMOVE COSMETIC REGULATORY BARRIERS EXPEDITE ASIA MARKET ACCESS

- In-time regulatory information and market access requirements
- Supported by local and experienced technically adept technical team
- Strategic partnerships with competent authorities and industrial associations worldwide
- Customized consulting service for complete compliance solutions.

OUR SERVICES

Information & Knowledge

News, Reports, Expert Analysis
Pedia-articles

Databases

Regulatory Database, English Translations
Inventories/Lists

Solutions

Regulatory Compliance Service, On-demand Translation, Advertisement Service,Tailor-made Service, E-commerce Solution

Training

Webinars, Online Course
Offline Events

CHEMLINKED.COM

14th Floor, Building 3, Haichuang Technology Center, 1288 West Wen Yi Road, Hangzhou, China (311121)
Tel: +86 (0)571 8609 4444 / Fax: +86 571 8700 7566 / E-mail: cosmetic@chemlinked.com
Visit our website for more information about AP cosmetic news & regulation updates