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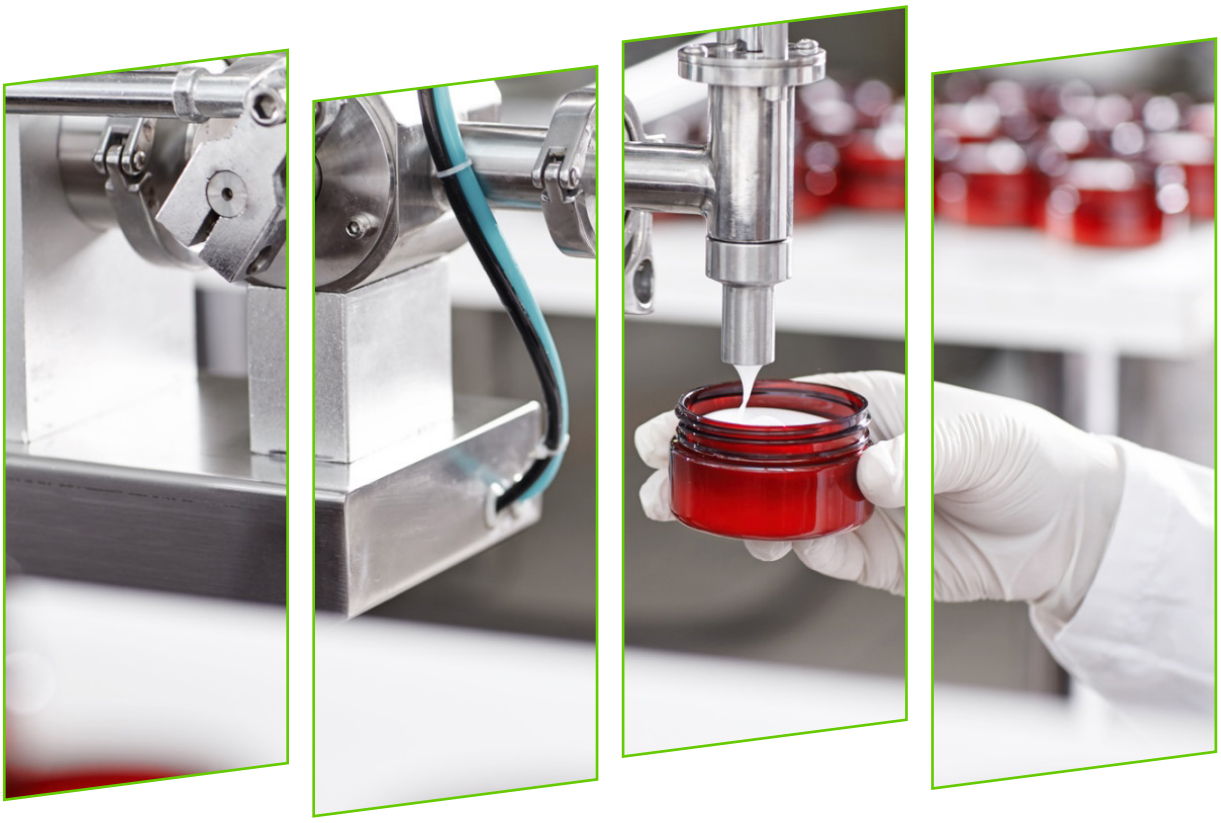

Supervision and Administration Measures on Cosmetics Manufacture and Operation

化妆品生产经营监督管理办法

State Administration for Market Regulation

Release Date: Aug. 2, 2021
Implementation Date: Jan. 1, 2022

Translated by ChemLinked

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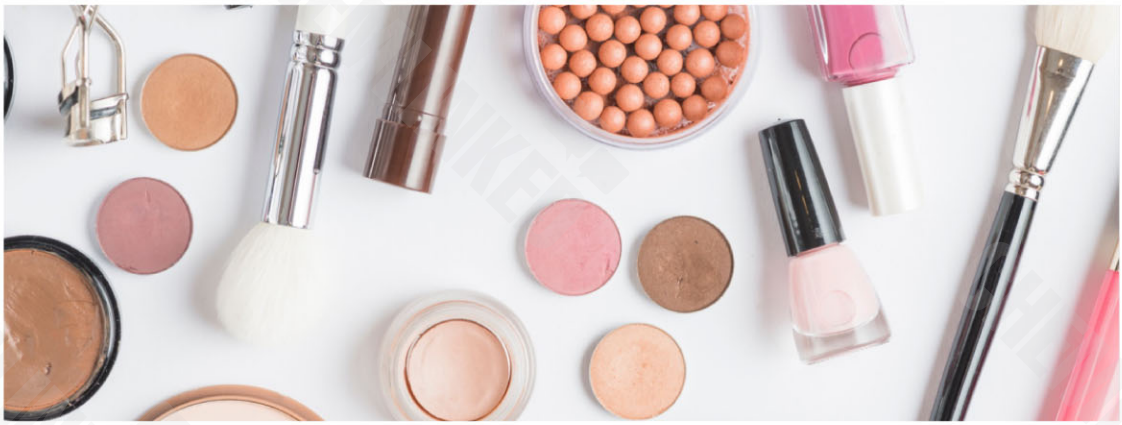

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Decree of the State Administration for Market Regulation

No.46

Supervision and Administration Measures on Cosmetics Manufacture and Operation of Cosmetics, as adopted at the 12th executive meeting of the State Administration for Market Regulation on July 26, 2021, is hereby promulgated and shall come into force as of January 1, 2022.

Director Zhang Gong

August 2, 2021

Supervision and Administration Measures on Cosmetics Manufacture and Operation

(Promulgated by Decree No. 46 of the State Administration for Market Regulation on August 2, 2021)

Chapter I General Provisions

Article 1 These Measures are formulated according to the *Cosmetic Supervision and Administration Regulations* to standardize the production and operation activities of cosmetics, strengthen the supervision and administration of cosmetics, and ensure the quality and safety of cosmetics.

Article 2 These Measures shall be observed in the production and operation activities of cosmetics and their supervision and administration within the territory of the People's Republic of China.

Article 3 The National Medical Products Administration shall be responsible for the supervision and administration of cosmetics nationwide.

The medical products administration departments of the local people's governments at or above the county level shall be responsible for the supervision and administration of cosmetics in their respective administrative regions.

Article 4 The cosmetic registrants and notifiers shall establish a cosmetic production quality management system in accordance with the law, fulfill the obligations of product adverse reaction monitoring, risk control, product recalls, *etc*., and be responsible for the quality, safety and efficacy claims of cosmetics. The cosmetic producers and operators shall engage in production and operation activities in accordance with the laws, regulations, rules, mandatory national standards and technical specifications, strengthen management, be honest and self-discipline, and ensure the quality and safety of cosmetics.

Article 5 The state implements licensing management for the production of cosmetics. To engage in cosmetic production activities, a cosmetic production license shall be obtained in accordance with the law.

Article 6 The cosmetic producers and operators shall, in accordance with the law, establish purchase inspection and recording system and product sales recording system, *etc*., to ensure product traceability.

The cosmetic producers and operators are encouraged to adopt information technology to collect and store production and operation information, and establish cosmetic quality and safety traceability system.

Article 7 The National Medical Products Administration shall strengthen the information construction and provide convenient services for the public to inquire about cosmetic information.

The medical products administration departments shall promptly publish the supervision and administration information regarding cosmetic production license, supervision and inspection, and administrative punishment, *etc*., in accordance with the law.

Article 8 The medical products administration departments shall give full play to the role of industry associations, consumer associations and other consumer organizations, news media, *etc*., push the establishment of a credit system, and promote social co-governance for cosmetic safety.

Chapter II Production Licensing

Article 9 To apply for a cosmetic production license, the following conditions shall be met:

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+ Product registration and filing
+ New cosmetic ingredient registration

+ 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

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国家市场监督管理总局令

第 46 号

《化妆品生产经营监督管理办法》已经 2021 年 7 月 26 日市场监管总局第 12 次局务会议通过，现予公布，自 2022 年 1 月 1 日起施行。

局长 张工

2021 年 8 月 2 日

化妆品生产经营监督管理办法

（2021 年 8 月 2 日国家市场监督管理总局令第 46 号公布）

第一章 总 则

第一条 为了规范化妆品生产经营活动，加强化妆品监督管理，保证化妆品质量安全，根据《化妆品监督管理条例》，制定本办法。

第二条 在中华人民共和国境内从事化妆品生产经营活动及其监督管理，应当遵守本办法。

第三条 国家药品监督管理局负责全国化妆品监督管理工作。

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监督管理工作。

第四条 化妆品注册人、备案人应当依法建立化妆品生产质量管理体系，履行产品不良反应监测、风险控制、产品召回等义务，对化妆品的质量安全和功效宣称负责。化妆品生产经营者应当依照法律、法规、规章、强制性国家标准、技术规范从事生产经营活动，加强管理，诚信自律，保证化妆品质量安全。

第五条 国家对化妆品生产实行许可管理。从事化妆品生产活动，应当依法取得化妆品生产许可证。

第六条 化妆品生产经营者应当依法建立进货查验记录、产品销售记录等制度，确保产品可追溯。

鼓励化妆品生产经营者采用信息化手段采集、保存生产经营信息，建立化妆品质量安全追溯体系。

第七条 国家药品监督管理局加强信息化建设，为公众查询化妆品信息提供便利化服务。

负责药品监督管理的部门应当依法及时公布化妆品生产许可、监督检查、行政处罚等监督管理信息。

第八条 负责药品监督管理的部门应当充分发挥行业协会、消费者协会和其他消费者组织、新闻媒体等的作用，推进诚信体系建设，促进化妆品安全社会共治。

第二章　生产许可

第九条　申请化妆品生产许可，应当符合下列条件：

（一）是依法设立的企业；

（二）有与生产的化妆品品种、数量和生产许可项目等相适应的生产场地，且与有毒、有害场所以及其他污染源保持规定的距离；

（三）有与生产的化妆品品种、数量和生产许可项目等相适应的生产设施设备且布局合理，空气净化、水处理等设施设备符合规定要求；

（四）有与生产的化妆品品种、数量和生产许可项目等相适应的技术人员；

（五）有与生产的化妆品品种、数量相适应，能对生产的化妆品进行检验的检验人员和检验设备；

（六）有保证化妆品质量安全的管理制度。

第十条　化妆品生产许可申请人应当向所在地省、自治区、直辖市药品监督管理部门提出申请，提交其符合本办法第九条规定条件的证明资料，并对资料的真实性负责。

第十一条　省、自治区、直辖市药品监督管理部门对申请人提出的化妆品生产许可申请，应当根据下列情况分别作出处理：

（一）申请事项依法不需要取得许可的，应当作出不予受理的决定，出具不予受理通知书；

（二）申请事项依法不属于药品监督管理部门职权范围的，应当作出不予受理的决定，出具不予受理通知书，并告知申请人向有关行政机关申请；

（三）申请资料存在可以当场更正的错误的，应当允许申请人当场更正，由申请人在更正处签名或者盖章，注明更正日期；

（四）申请资料不齐全或者不符合法定形式的，应当当场或者在 5 个工作日内一次告知申请人需要补正的全部内容以及提交补正资料的时限。逾期不告知的，自收到申请资料之日起即为受理；

（五）申请资料齐全、符合法定形式，或者申请人按照要求提交全部补正资料的，应当受理化妆品生产许可申请。

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