



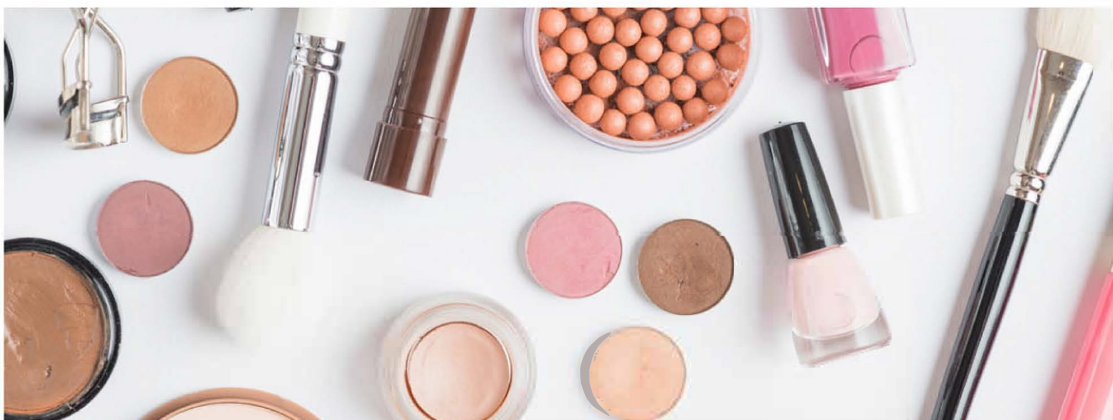
Guidelines for Handling Approval of Registration Renewal of Imported Special Cosmetics

进口特殊化妆品延续注册审批办事指南

National Institutes for Food and Drug Control

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Implementation Date: Jun 5, 2023

Translated by ChemLinked



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Guidelines for Handling Approval of Registration Renewal of Imported Special Cosmetics

I. Name and Code of the Administrative Licensing Item

Approval of Registration of Special Cosmetics (00017214900Y)

(I) **Name of the Licensing Item:** Approval of Registration Renewal of Imported Special Cosmetics

(II) **Code of Handling Guidelines:** _____

(III) **Implementation List for the Corresponding Government Service Item:** _____

(IV) **Implementation Code:** 11100000MB0341032Y1000172046001

(V) **Code of the Business Handling Item:** 11100000MB0341032Y100017204600102

II. Subitem Name and Code of the Administrative Licensing Item and Business Handling Item

(I) **Subitem:** Approval of Registration of Imported Special Cosmetics (000172149002)

(II) **Business Handling Item:** Approval of Registration Renewal of Imported Special Cosmetics

III. Competent Authority

National Medical Products Administration (NMPA)

IV. Basis for Setting and Implementation

(I) Setting Basis:

Article 4 of the *Cosmetic Supervision and Administration Regulations (CSAR)*: Classified management is implemented for cosmetics and new cosmetic ingredients according to the degree of risk in China. Registration management and notification management are respectively implemented for special cosmetics and general cosmetics;

Article 17: Special cosmetics can only be produced and imported after being registered with the medical products administration department of the State Council.

(II) Implementation Basis:

Article 17 of the *CSAR*: Special cosmetics can only be produced and imported after being registered with the medical products administration department of the State Council.

(III) Regulatory Basis:

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1. Article 64 of the CSAR: If any false information is provided or other deceptive means are adopted when applying for administrative license for cosmetics, the administrative license shall not be granted; if administrative license has already been obtained, the administrative license shall be revoked by the department that made the decision on granting the administrative license, and the cosmetics related license application submitted by the applicant shall not be accepted within 5 years, while its illegal gains and cosmetics already produced or imported shall be confiscated. Where the value of the cosmetics already produced or imported is less than 10,000 yuan, a fine between 50,000 yuan and 150,000 yuan shall be imposed; where the value of the cosmetics exceeds 10,000 yuan, a fine of 15 to 30 times the value of the cosmetics shall be imposed. The legal representative or main person in charge, directly responsible person in charge, and other directly responsible persons of the unit involved in violations shall be fined not less than 3 times but not more than 5 times the income thereof obtained from the unit in the previous year, and they shall be prohibited from engaging in cosmetic production and operation activities for life.

Article 24 of the CSAR: The period of validity is 5 years for the registration certificate for special cosmetics. If the registration needs to be renewed upon the expiration of the period of validity, an application for renewal shall be submitted 30 working days before the expiration of the period. Except for the situations stipulated in the second paragraph of this article, a decision shall be made by the medical products administration department of the State Council on approving the renewal of the registration certificate for special cosmetics before the expiration of its period of validity; if no decision is made within the deadline, it shall be deemed as having approved the renewal. When one of the following situations occurs, the registration renewal shall not be granted: (I) the registrant fails to submit an application for renewal of registration within the prescribed time limit; (II) the mandatory national standards and technical standards have been revised, and the cosmetics involved in application for renewal of registration cannot meet the requirements of these revised standards.

Article 6 of the *Administrative Measures on Cosmetic Registration and Notification*: The medical products administration departments of provinces, autonomous regions, and municipalities directly under the Central Government shall be responsible for the notification management of domestically produced general cosmetics within their respective administrative regions. They shall, within the scope of entrustment, implement the notification management of imported general cosmetics in the name of the NMPA, and assist in on-site verification of registration of special cosmetics.

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- + New cosmetic ingredient (NCI) registration and notification
- + 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
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- + California Safe Cosmetics Program (CSCP)
- + Toxicological Risk Assessment (TRA)
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进口特殊化妆品延续注册审批办事指南

一、行政许可事项名称及编码

特殊化妆品注册审批 (00017214900Y)

- (一) 许可事项名称: 进口特殊化妆品延续注册审批
- (二) 办事指南编码: _____
- (三) 对应政务服务事项实施清单: _____
- (四) 实施编码: 11100000MB0341032Y1000172046001
- (五) 业务办理项编码: 11100000MB0341032Y100017204600102

二、行政许可事项的子项名称及编码、业务办理项

- (一) 子项: 进口特殊化妆品注册审批 (000172149002)
- (二) 业务办理项: 进口特殊化妆品延续注册审批

三、主管部门

国家药监局

四、设定和实施依据

(一) 设定依据:

《化妆品监督管理条例》第四条: 国家按照风险程度对化妆品、化妆品新原料实行分类管理。国家对特殊化妆品实行注册管理, 对普通化妆品实行备案管理;

第十七条: 特殊化妆品经国务院药品监督管理部门注册后方可生产、进口。

(二) 实施依据:

《化妆品监督管理条例》第十七条: 特殊化妆品经国务院药品监督管理部门注册后方可生产、进口。

(三) 监管依据:

1. 《化妆品监督管理条例》第六十四条: 在申请化妆品行政许可时提供虚假资料或者采取其他欺骗手段的, 不予行政许可, 已经取得行政许可的, 由作出行政许可决定的部门撤销行政许可, 5 年内不受理其提出的化妆品相关许可申请, 没收违法所得和已经生产、进口的化妆品; 已经生产、进口的化妆品货值金额不足 1 万元的, 并处 5 万元以上 15 万元以下罚款; 货值金额 1 万元以上的, 并处货值金额 15 倍以上 30 倍以下罚款; 对违法单位的法定代表人或者主要负责人、直接负责的主管人员和其他直接

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责任人员处以其上一年度从本单位取得收入的 3 倍以上 5 倍以下罚款，终身禁止其从事化妆品生产经营活动。

《化妆品监督管理条例》第二十四条：特殊化妆品注册证有效期为 5 年。有效期届满需要延续注册的，应当在有效期届满 30 个工作日前提出延续注册的申请。除有本条第二款规定情形外，国务院药品监督管理部门应当在特殊化妆品注册证有效期届满前作出准予延续的决定；逾期未作决定的，视为准予延续。有下列情形之一的，不予延续注册：（一）注册人未在规定期限内提出延续注册申请；（二）强制性国家标准、技术规范已经修订，申请延续注册的化妆品不能达到修订后标准、技术规范的要求。

《化妆品注册备案管理办法》第六条：省、自治区、直辖市药品监督管理部门负责本行政区域内国产普通化妆品备案管理工作，在委托范围内以国家药品监督管理局的名义实施进口普通化妆品备案管理工作，并协助开展特殊化妆品注册现场核查等工作。

第四十八条：特殊化妆品取得注册证后，注册人应当在产品投放市场前，将上市销售的产品标签图片上传至信息服务平台，供社会公众查询。

2.《中华人民共和国行政许可法》第七十八条：行政许可申请人隐瞒有关情况或者提供虚假材料申请行政许可的，行政机关不予受理或者不予行政许可，并给予警告；行政许可申请属于直接关系公共安全、人身健康、生命财产安全事项的，申请人在一年内不得再次申请该行政许可。

五、实施机关

国家药监局

- （一）权力来源：法定本级行使
- （二）实施主体：国家药品监督管理局
- （三）实施主体性质：法定机关
- （四）实施主体编码：11100000MB0341032Y

六、审批层级

- （一）审批层级：国家级
- （二）行使层级：国家级
- （三）受理层级：国家级
- （四）初审层级：无

七、行政许可事项类型（不对外公开）

条件型

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