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Inspection Points and Judgment Principles of Cosmetic Good Manufacturing Practices (Draft for Comments)

化妆品生产质量管理规范检查要点及判定原则（征求意见稿）

National Medical Products Administration

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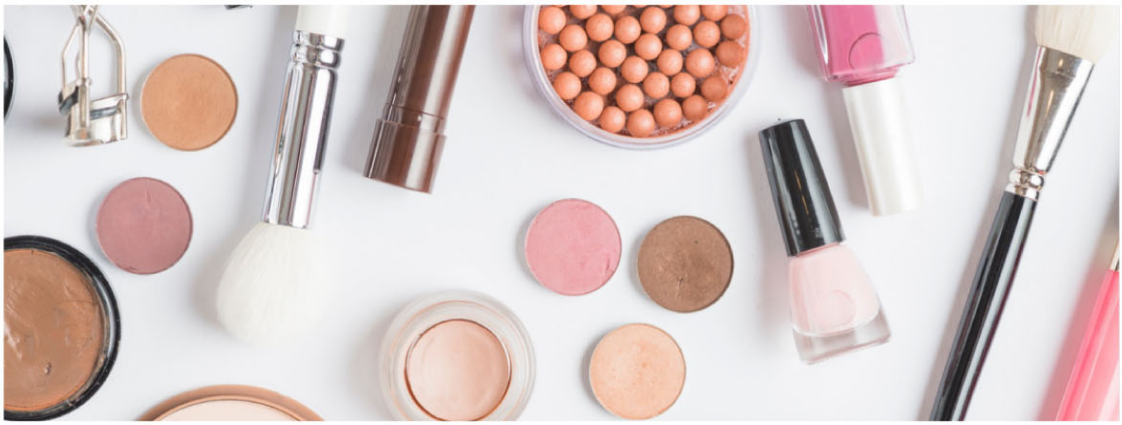

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Annex 1

Inspection Points and Judgment Principles of Cosmetic Good Manufacturing Practices

(Draft for Comments)

In order to regulate the quality management of cosmetics production and protect the legitimate rights and interests of cosmetics producers and operators, the National Medical Products Administration has organized and formulated the *Inspection Points and Judgment Principles of Cosmetic Good Manufacturing Practices* in accordance with the *Cosmetic Supervision and Administration Regulations* (CSAR), *Supervision and Administration Measures on Cosmetics Manufacture and Operation* and other laws and regulations and rules for implementation of the *Good Manufacturing Practices for Cosmetics (the Practices)*.

I. Application Scope of Inspection Points

(I) Inspection of cosmetics registrants, notifiers and entrusted production enterprises engaged in cosmetics production activities in accordance with the "Inspection Points of Cosmetic Good Manufacturing Practices" (Actual Production, see Attachment 1). Attachment 1 lists 82 inspection items in total, covering 29 key items (including 5 critical items and 24 other key items) and 53 general items.

(II) Inspection of cosmetics registrants and notifiers entrusting production in accordance with the "Inspection Points of Cosmetic Good Manufacturing Practices" (Entrusted Production, see Attachment 2). Attachment 2 lists 24 inspection items in total, covering 9 key items (including 2 critical items and 7 other key items) and 15 general items.

(III) Separate inspection of cosmetics registrants and notifiers both engaged in cosmetics production activities and entrusting production respectively in accordance with the Attachments 1 and 2.

II. Inspection Classification and Judgment Principles

(I) On-site inspection of production license

Medical products administration departments shall conduct on-site inspection of production license for cosmetics production license applicants in accordance with Attachment 1. After inspection, if all inspection items comply with the provisions, the applicants shall be judged as “eligible for cosmetics production license”.

If one of the following circumstances exists, the applicants shall be judged as “ineligible for cosmetics production license”:

1. Having 1 or more critical items not complying with the provisions;

2. Having 6 or more defective critical items and other key items not complying with the provisions in total;

3. Having 16 or more key items not complying with the provisions, defective key items, and general items not complying with the provisions in total.

(II) On-site inspection after renewal of production license

Medical products administration departments of provinces, autonomous regions and municipalities directly under the Central Government shall, within 6 months from the date of re-issuing new cosmetics production license to the applicants for the renewal of cosmetics production license, conduct on-site inspection of the enterprises in accordance with Attachment 1. If the inspection result complies with one of the above three circumstances of “ineligible for cosmetics production license”, the medical products administration departments shall revoke the cosmetics production license thereof in accordance with the law.

(III) Daily supervision and inspection

1. Supervision and inspection of cosmetics registrants, notifiers and entrusted production

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附件 1

化妆品生产质量管理规范
检查要点及判定原则
(征求意见稿)

为规范化妆品生产质量管理，保障化妆品生产经营者的合法权益，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，落实《化妆品生产质量管理规范》，国家药监局组织制定了《化妆品生产质量管理规范检查要点及判定原则》。

一、检查要点适用范围

（一）对从事化妆品生产活动的化妆品注册人、备案人、受托生产企业，依据化妆品生产质量管理规范检查要点（实际生产版，见附 1）开展检查。附 1 共有检查项目 82 项，其中重点项目 29 项（重点项目包括关键项目 5 项，其他重点项目 24 项），一般项目 53 项。

（二）对委托生产的化妆品注册人、备案人，依据化妆品生产质量管理规范检查要点（委托生产版，见附 2）开展检查。附 2 共有检查项目 24 项，其中重点项目 9 项（重点项目包括关键项目 2 项，其他重点项目 7 项），一般项目 15 项。

（三）对既从事化妆品生产活动又委托生产的化妆品注册人、备案人，依据附 1 和附 2 分别开展检查。

二、检查分类及判定原则

（一）生产许可现场核查

负责药品监督管理的部门应当依据附 1 对化妆品生产许可申请人开展生产许可现场核查。经核查，检查项目均符合规定的，应当判定为“符合化妆品生产许可条件”。

存在以下情形之一的，应当判定为“不符合化妆品生产许可条件”：

1.存在 1 项（含）以上关键项目不符合规定的；

2.存在关键项目瑕疵数与其他重点项目不符合规定数总和大于 6 项（含）的；

3.重点项目不符合规定数、重点项目瑕疵数、一般项目不符合规定数总和大于 16 项（含）的。

（二）生产许可延续后现场核查

省、自治区、直辖市药品监督管理部门应当在其向化妆品生产许可延续申请人换发新化妆品生产许可证之日起 6 个月内，依据附 1 组织对该企业开展现场核查，核查结果为上述“不符合化妆品生产许可条件”三种情形之一的，应当依法撤销化妆品生产许可。

（三）日常监督检查

1.对从事化妆品生产活动的化妆品注册人、备案人、受托生产企业监督检查

负责药品监督管理的部门应当依据附 1 对已取得化妆品生产许可证的企业生产质量管理规范执行情况开展全部或者部分项目监督检查；

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