



Guidelines for Preparing Self-Inspection Reports on Cosmetic Adverse Reactions by Cosmetics Registrants and Notifiers

化妆品注册人、备案人化妆品不良反应自查报告撰写指南

National Center for Adverse Drug Reaction
(ADR) Monitoring

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Guidelines for Preparing Self-Inspection Reports on Cosmetic Adverse Reactions by Cosmetics Registrants and Notifiers

1. Purpose

The *Guidelines* is formulated in accordance with the relevant provisions of the *Cosmetic Supervision and Administration Regulation (CSAR)*, the *Supervision and Administration Measures on Cosmetics Manufacture and Operation*, the *Measures for the Management of Cosmetic Adverse Reaction Monitoring*, and other relevant regulations to standardize and guide cosmetics registrants and notifiers in preparing self-inspection reports on cosmetic adverse reactions.

2. Scope of Application

The *Guidelines* applies to cosmetics registrants and notifiers in the preparation of self-inspection reports on cosmetic adverse reactions within the territory of the People's Republic of China, and are intended to help them understand and master the basic requirements and contents of such reports.

3. General Requirements

Cosmetics registrants and notifiers shall analyze and evaluate cosmetic adverse reactions that they discover or become aware of and, where necessary, conduct self-inspections to identify possible causes of such adverse reactions relating to cosmetic ingredients, formulas, manufacturing processes, production quality management, storage and transportation, and other relevant aspects. Chinese domestic responsible persons shall actively assist overseas cosmetics registrants and notifiers in analyzing and evaluating cosmetic adverse reactions that they discover or become aware of.

For serious cosmetic adverse reactions, cosmetics registrants and notifiers shall, within 20 days from the date on which they discover or become aware of the adverse reaction, complete the analysis and evaluation, prepare a self-inspection report, and submit it to the provincial-level monitoring institution in the locality where the cosmetics registrant, notifier, or Chinese domestic responsible person is located, with a copy submitted concurrently to the provincial-level medical products administration department in the same locality. For cosmetic adverse reactions that may cause significant social impact, the analysis and evaluation and the preparation of a self-inspection report shall be

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化妆品注册人、备案人

化妆品不良反应自查报告撰写指南

1. 目的

为规范和指导化妆品注册人、备案人开展化妆品不良反应自查报告撰写工作，依据《化妆品监督管理条例》《化妆品生产经营监督管理办法》《化妆品不良反应监测管理办法》等有关规定，制定本指南。

2. 适用范围

本指南适用于指导化妆品注册人、备案人在中华人民共和国境内开展化妆品不良反应自查报告撰写工作，帮助其理解和掌握自查报告撰写的基本要求和内容。

3. 总体要求

化妆品注册人、备案人应当对发现或者获知的化妆品不良反应进行分析评价，必要时自查产品原料、配方、生产工艺、生产质量管理、贮存运输等方面可能引发不良反应的原因。境内责任人应当积极协助境外化妆品注册人、备案人对发现或者获知的化妆品不良反应进行分析评价。

属于严重化妆品不良反应的，化妆品注册人、备案人应当自发现或者获知不良反应之日起 20 日内，属于可能引发较大社会影响的化妆品不良反应的，应当自发现或者获知不良反应之日起 10 日内进行分析评价并形成自查报告，报送化妆品注册人、备案人、境内责任人所在地省级监测机构，同时报送所在地省级药监部门。

4. 自查报告内容

根据化妆品不良反应的具体情况，化妆品注册人、备案人按照以下内容及参考格式（见附件 1）撰写自查报告。



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