



Technical Guidelines for Research on Anti-Hair Loss Cosmetics (Trial)

《防脱发化妆品研究技术指导原则（试行）》

National Institutes for Food and Drug Control

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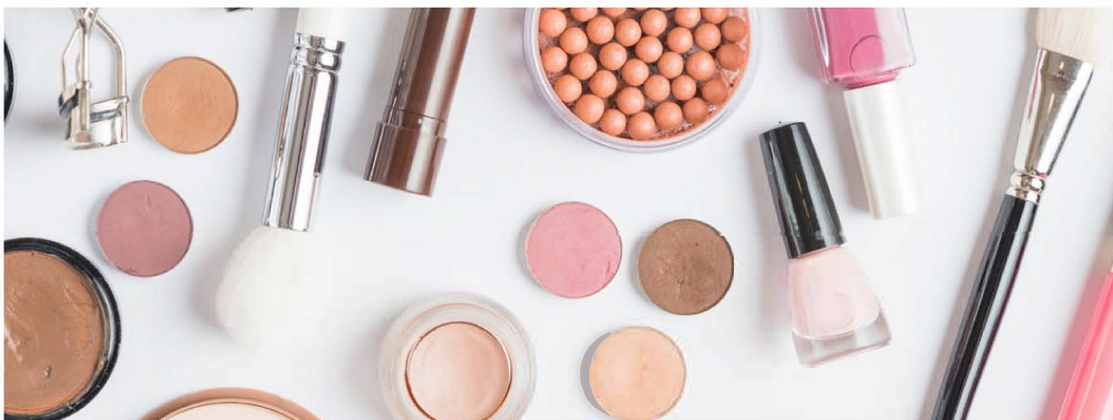
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Attachment 1

**Technical Guidelines for Research on Anti-Hair Loss Cosmetics
(Trial)**

National Institutes for Food and Drug Control

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I. Introduction

In accordance with the *Cosmetic Supervision and Administration Regulation* (CSAR), anti-hair loss cosmetics are classified as special cosmetics and subject to registration management. For the purpose of standardizing and guiding the research on anti-hair loss cosmetics, these guidelines are hereby formulated.

These guidelines are formulated based on existing regulations and standards, and the current level of scientific cognition. Relevant contents will be adjusted in a timely manner with the continuous improvement of regulations and standards, and development of science and technology.

II. Application Scope

In accordance with the interpretive notes and claim guides set forth in the *Cosmetic Classification Rules and Catalog* (hereinafter referred to as the *Classification Catalog*), anti-hair loss mainly refers to helping improve or reduce hair loss, and products with such efficacy are managed as special cosmetics; anti-hair breakage refers to helping improve or reduce hair breakage and splitting, maintaining or enhancing hair tenacity, and products with such efficacy are managed as general cosmetics. Products that regulate hormone impacts and promote hair growth do not belong to cosmetics. These guidelines apply to the research on anti-hair loss cosmetics.

Registrants shall apply these guidelines under the premise of complying with relevant laws, administrative regulations, mandatory national standards, and technical standards. If there are other applicable technical guidelines for the relevant contents, the technical requirements in the corresponding guidelines shall also be referred to simultaneously.

III. General Principles

Registrants shall conduct thorough research on anti-hair loss cosmetics surrounding the technical contents such as product quality, safety, efficacy, and labeling claims in compliance with relevant provisions including CSAR, the *Provisions for Management of Cosmetic Registration and Notification Dossiers* (hereinafter referred to as the *Provisions*), the *Working Rules for Cosmetic Registration and Notification Testing* (hereinafter referred to as the *Testing Rules*), the *Safety and Technical Standards for Cosmetics* (STSC), the *Standards for Cosmetics Efficacy Claim Evaluation*, the *Administrative Measures on Cosmetic Labeling* (hereinafter referred to as the *Labeling Administrative Measures*), etc. to ensure that consumers can use such cosmetics correctly and acquire the expected

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- + Label & advertisement review



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- + 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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附件 1

**防脱发化妆品研究技术指导原则
(试行)**

中国食品药品检定研究院

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一、前言

根据《化妆品监督管理条例》（以下简称《条例》），防脱发化妆品属于特殊化妆品，实行注册管理。为规范和指导防脱发化妆品研究，制定本指导原则。

本指导原则是在现行法规、标准以及当前科学认知水平下制定的，随着法规、标准的不断完善以及科学技术的不断发展，相关内容将适时进行调整。

二、适用范围

根据《化妆品分类规则和分类目录》（以下简称《分类目录》）中的释义说明和宣称指引，防脱发主要是指有助于改善或减少头发脱落，具有此类功效的产品按照特殊化妆品管理；防断发是指有助于改善或减少头发断裂、分叉，有助于保持或增强头发韧性，具有此类功效的产品按照普通化妆品管理；调节激素影响的产品，促进生发作用的产品，不属于化妆品范畴。本指导原则适用于防脱发化妆品的研究。

注册人应在遵循相关法律、行政法规、强制性国家标准和技术规范的前提下使用本指导原则。如相关内容同时符合其他技术指导原则适用范围的，还应同时参考相应指导原则的技术要求。

三、一般原则

注册人应按照《条例》《化妆品注册备案资料管理规定》（以下简称《资料管理规定》）《化妆品注册和备案检验工作规范》（以下简称《检验规范》）《化妆品安全技术规范》（以下简称《技术规范》）《化妆品功效宣称评价规范》《化妆品标签管理办法》（以下简称《标签管理办法》）等有关规定，围绕产品的质量、安全、功效、标签宣称等技术内容，对防脱发化妆品开展充分研究，确保消费者能够正确使用并取得预期效果。

四、主要内容

防脱发化妆品研究内容主要包括质量可控性、安全性、产品功效评价和标签宣称等。

（一）质量可控性研究

防脱发化妆品质量可控性研究主要包括原料、配方、生产工艺与质量控制。

1. 原料

原料的选择及使用应契合产品剂型特点，并符合《技术规范》等相关法律法规和技术标准要求，应根据原料在产品中实际发挥的主要作用明确其主要使用目的，确保使用目的与原料理化性质、产品属性相符。



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