



Technical Guidelines for Research on Efficacy-Related Ingredients of Anti-Hair Loss Cosmetics (Trial) (Draft for Comments)

防脱发化妆品功效相关原料研究技术指导原则
(试行) (征求意见稿)

National Institutes for Food and Drug Control

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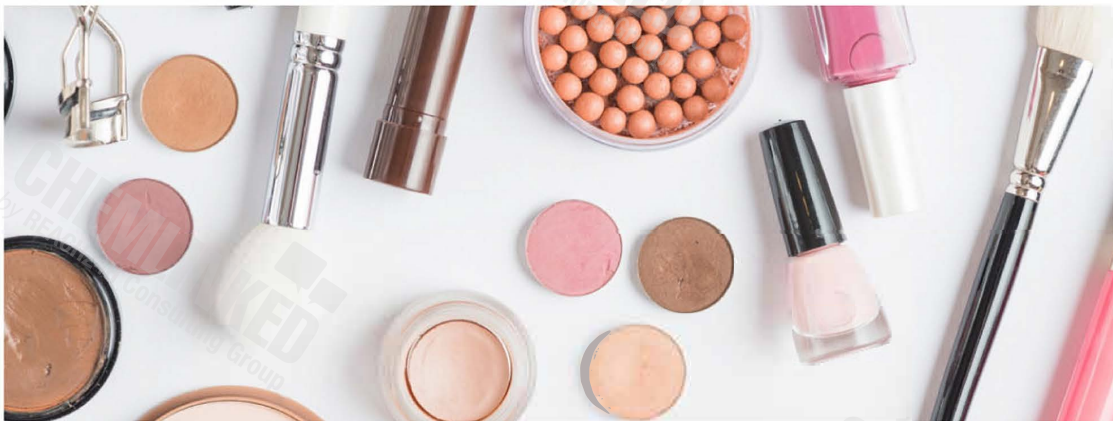
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Attachment 3

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I. Introduction

In accordance with the *Cosmetic Supervision and Administration Regulations (CSAR)*, anti-hair loss cosmetics are classified as special cosmetics and subject to registration management. The material basis for such cosmetics to exert an anti-hair loss efficacy is the related ingredients in the formulas that have an anti-hair loss efficacy. Therefore, the selection and research of efficacy-related ingredients are the prerequisites for product formula design and research. For the purpose of standardizing and guiding research on efficacy-related ingredients of 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 content will be adjusted in a timely manner with the continuous improvement of regulations and standards, and the development of science and technology.

II. Application Scope

These guidelines apply to the research on anti-hair loss efficacy-related ingredients in anti-hair loss cosmetic formulas. Anti-hair loss efficacy-related ingredients fall into two categories: the first category includes ingredients with a clearly demonstrated anti-hair loss effect, or components with an anti-hair loss effect in non-single component ingredients, i.e., the “anti-hair loss agents” filled out in the formulas; the second category refers to ingredients that play an auxiliary role in exerting the anti-hair loss effect in the products confirmed to have an anti-hair loss effect, namely the “anti-hair loss adjuvants” filled out in the formulas.

Registration applicants 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, the technical requirements in the corresponding guidelines shall also be referred to simultaneously.

III. General Principles

The research on anti-hair loss efficacy related ingredients in cosmetics shall be conducted surrounding the definition of the anti-hair loss efficacy. The research methods may refer to relevant regulatory documents or technical standards published or approved by domestic and foreign administration departments, or analysis and evaluation research may be conducted on the anti-hair loss efficacy-related ingredients used, including test studies.

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The research content shall include regulatory documents, technical standards, and literature, among others, with analysis of the provided dossiers; or necessary test studies can be carried out to ensure the scientificity and rationality of the use of anti-hair loss efficacy related ingredients in cosmetics. In addition, registration applicants shall carry out safety assessment on anti-hair loss efficacy related ingredients, or necessary toxicological test studies and human body safety tests, to ensure the safety of the use of anti-hair loss efficacy related ingredients in cosmetics.

Registration applicants shall retain relevant dossiers for future reference, or agree with ingredient manufacturers, suppliers, research institutions, or other organizations to have them retain the relevant dossiers and cooperate in providing them at any time. For the use of unpublished research data or reports provided by third parties, authorization shall be obtained from these third parties, or there shall be a clear entrustment relationship. Registration applicants shall be responsible for the authenticity, accuracy, completeness, and traceability of relevant dossiers.

IV. Research Methods for Efficacy-Related Ingredients

(I) Research with Reference to Regulatory Documents or Technical Standards

The research on the filled “anti-hair loss agents” can refer to relevant regulatory documents or technical standards published or approved by domestic and foreign administration departments. Under such reference, registration applicants shall judge the source of the information and its authority, reliability, and traceability, and shall adopt regulatory documents or technical standards with clear sources and definite formulation procedures. Registration applicants shall have a detailed understanding of the specific situation and use requirements of the ingredients included in the regulatory documents or technical standards, and in combination with the actual ingredients used and their actual application in formulas, judge and specify item by item in the dossiers whether the relevant regulatory documents or technical standards are referable, including but not limited to ingredient composition, quality specification, use amount and scope, and other restrictive conditions. For non-single-component ingredients such as plant extracts, effective quality control shall be implemented to ensure ingredient safety and efficacy stability.

(II) Analysis and Evaluation on Efficacy-Related Ingredients of Anti-Hair Loss Cosmetics

1. General Requirements

The analysis and evaluation research on anti-hair loss efficacy-related ingredients shall



Free



Free trial



Standard



Corporate



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