



Technical Guidelines for Special Cosmetics with Freckle-removing and Whitening Efficacy (Draft for Comments)

祛斑美白类特殊化妆品技术指导原则（征求意见稿）

National Institutes for Food and Drug Control

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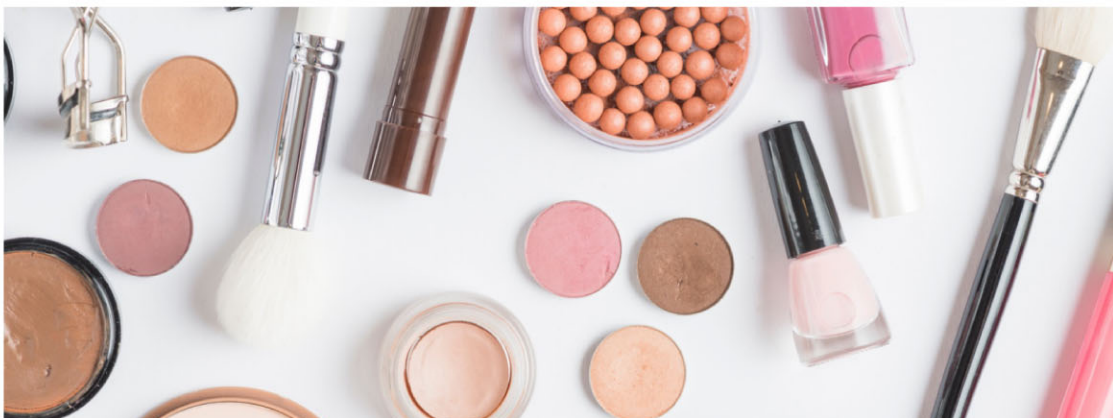
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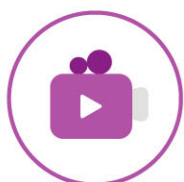


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These guidelines are formulated to provide specific technical guidance for the registrants of special cosmetics with freckle-removing and whitening efficacy during the registration application, and to provide a technical reference for the technical review department to review and verify the registration documents.

These guidelines are general technical requirements for special cosmetics with freckle-removing and whitening efficacy. They do not apply to cosmetics that achieve freckle-removing and whitening effect through physical covering. If the product applying for registration belongs to other special cosmetic categories at the same time, uses special ingredients or special techniques, applies to special populations or is subject to other technical guidelines, references shall also be made to the corresponding guideline requirements. The registrants shall prepare the documents in a comprehensive, accurate, meticulous and standardized manner in accordance with the *Administrative Measures on Cosmetics Registration and Notification, Provisions for Management of Cosmetic Registration and Notification Dossiers* and requirements of relevant regulations and technical standards, as well as the specific characteristics and actual conditions of the product applying for the registration.

These guidelines are technical guidance documents for registrants and documents reviewers, and do not include the administrative matters involved in the application approval of registration. These guidelines shall be used under the premise of complying with relevant regulations and technical standards.

These guidelines are formulated under the current regulations and standards and at the current level of awareness. With the continuous improvement of regulations and standards, as well as the sustained development of science and technology, the relevant contents thereof may be adjusted in time.

1. Basic principles of freckle-removing and whitening

Human skin color is mainly determined by the type, quantity and distribution of melanin in skin. According to the interpretations and claim guidelines for "freckle-removing and whitening" in the *Cosmetic Classification Rules and Catalog*, freckle-removing and whitening is mainly defined as helpful in reducing or slowing down skin pigmentation, in addition to physical covering.

The freckle-removing and whitening cosmetics shall have a relatively mild and slight freckle-removing and whitening effect, meeting the definition of cosmetics. They shall regulate the production, transportation and metabolism of melanin in the skin to a certain extent by principles such as inhibiting tyrosinase activity, to achieve a certain freckle-

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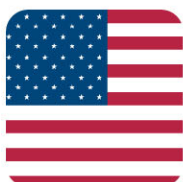
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- + Ingredients analysis and full ingredient list translation
- + Cosmetic test service
- + Label & advertisement review



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- + Cosmetic formula and label compliance review
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- + California Safe Cosmetics Program (CSCP)
- + Toxicological Risk Assessment (TRA)
- + INCI application

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祛斑美白类特殊化妆品 技术指导原则

(征求意见稿)

中国食品药品检定研究院

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本指导原则旨在为注册申请人进行祛斑美白类特殊化妆品的注册申报提供具体的技术指导，同时为技术审评部门基于注册申报资料开展审评和技术核查工作提供技术参考。

本指导原则是关于祛斑美白类特殊化妆品的一般技术要求，不适用于仅具物理遮盖作用的祛斑美白类产品。如申报产品同时属于其他特殊化妆品类别、使用特殊原料或特殊技术、用于特殊人群或适用于其他技术指导原则的，还应同时参考相应的指导原则要求。注册申请人应按照《化妆品注册备案管理办法》《化妆品注册备案资料管理规定》及相关法规和技术标准要求，同时根据申报产品的具体特性和实际情况，全面、准确、细致、规范地准备资料。

本指导原则是对注册申请人和审评人员的指导性技术文件，不包括注册申报审批所涉及的行政事项，应在遵循相关法规和技术标准的前提下使用。

本指导原则是在现行法规、标准以及当前认知水平下制定，随着法规和标准的不断完善以及科学技术的不断发展，相关内容将可能适时调整。

1. 祛斑美白作用基本原则

人体皮肤颜色主要由皮肤中黑色素的种类、数量和分布决定。根据《化妆品分类规则和分类目录》中关于“祛斑美白”的释义说明和宣称指引，除物理遮盖形式外，祛斑美白作用主要是指有助于减轻或减缓皮肤色素沉着。

祛斑美白类化妆品的祛斑美白作用应相对温和、轻微，应符合化妆品的定义，可以通过抑制酪氨酸酶活性等原理，有限度地调节皮肤中黑色素的产生、运输和代谢，从而达到一定的祛斑美白作用。不得以医疗为目的，不得对人体生理功能产生剧烈的或者不可逆的影响。

通过剥脱角质等方式，可能会促进含黑素小体的角质形成细胞向角质层方向移动，从而有助于加快黑色素从皮肤的排出进程。因此，在祛斑美白类化妆品中适当使用“角质剥落剂”，可辅助加强其祛斑美白作用，但该方式不作为一项祛斑美白作用机理，相关原料不应按照祛斑美白剂填报。

通过防晒作用，减轻外界紫外线损伤以及相应的皮肤应答，最终可能同时体现出一定的预防/减轻皮肤黑化或者晒斑的作用，但应属于防晒的次级结果，不作为直接的祛斑美白功效。

2. 祛斑美白类化妆品的界定

根据《化妆品分类规则和分类目录》以及上述祛斑美白作用基本原则，祛斑美白类化妆品主要是指有助于减轻或减缓皮肤色素沉着、达到皮肤美白增白效果的化妆品，改善因色素沉积导致痘印的产品也应作为祛斑美白类产品申报。

仅通过物理遮盖形式达到皮肤美白增白效果的，可申报“祛斑美白类（仅具物理遮盖作



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