



Several Provisions on Supporting Innovation in Cosmetic Ingredients

支持化妆品原料创新若干规定

National Medical Products Administration

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Attachment**Several Provisions on Supporting Innovation in Cosmetic Ingredients**

In order to implement the spirit of the Third Plenary Session of the 20th Central Committee of the CPC, further deepen reforms, and improve the mechanisms for innovative development of cosmetics, the *Provisions* is formulated with the focus on encouraging innovation in cosmetic ingredients and the goal of building a market demand-oriented collaborative innovation system for cosmetic ingredients.

I. Optimizing the Technological Requirements for Registration and Notification Classification of New Ingredients

The classification management and technological evaluation system for registration and notification of new cosmetic ingredients will be improved. The technological requirements will be optimized based on characteristics, functions, intended purposes, and innovative features of ingredients, and technological guidance will be strengthened for enterprises in terms of determination and classification research of new ingredients. The safety assessment requirements will be optimized for new ingredients used for the first time both domestically and overseas, taking into account the actual degree of risk. Based on scientific safety assessment conducted by enterprises, some toxicological and long-term human trial safety test requirements will be reduced or exempted. For new ingredients that have a sufficient history of safe use, the research on history of safe use and safe consumption and judgment standards will be clarified, the utilization of existing data will be strengthened, and the requirements for safety assessment will be simplified. As regards new ingredients from improvement and innovation of existing ingredients, the history of their safe use will be fully considered and corresponding technological requirements will be formulated. The way to change marketed new ingredients will be clarified and technological guidance principles for change research will be formulated.

II. Promoting Synchronous Application of New Ingredients and Related Products

The research correlation between new ingredients and cosmetics will be strengthened, the efficiency of review and approval of new ingredients and cosmetics will be improved, and the marketing of products using new ingredients will be accelerated. For new cosmetic ingredients applied for registration, submission of registration applications for special cosmetics using these new ingredients will be encouraged; if notified new cosmetic

ChemLinked Team, REACH24H Consulting Group

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- + INCI application

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附件

支持化妆品原料创新若干规定

为贯彻落实党的二十届三中全会精神，进一步深化改革，健全化妆品创新发展机制，以鼓励化妆品原料创新为重点，以构建市场需求为导向的化妆品原料协同创新体系为目标，制定本规定。

一、优化新原料注册备案分类技术要求

完善化妆品新原料注册备案分类管理和技术评价体系。根据原料特性、功能、预期用途和创新特点，优化技术要求，加强对企业新原料判定及分类研究的技术指导。对国内外首次使用的新原料，结合实际风险程度优化新原料安全评价相关要求，在企业科学开展安全评估的基础上，减免部分毒理学和长期人体试用安全试验相关要求；对已有充分安全使用历史的新原料，明确安全使用、安全食用历史研究和判定标准，加强已有数据利用，简化安全性评价相关要求；对已使用原料改进创新的新原料，充分考虑安全使用历史，制定相应技术要求。明确已上市新原料变更路径，制定变更研究技术指导原则。

二、推进新原料与关联产品同步申报

加强新原料和化妆品相关研究关联，提高新原料和化妆品审评审批效率，加速推进使用新原料的产品上市。对申请注册的化妆品新原料，鼓励同时提出使用该新原料特殊化妆品的注册申请；备案的化妆品新原料用于特殊化妆品的，可以在进行新原料备案的同时提出特殊化妆品注册申请。优化升级化妆品智慧审评系统，为新原料注册备案以及使用新原料的特殊化妆品注册申报提供更多便利服务。

三、加强新原料创新服务和应用转化

支持新原料创新和应用，对符合一定条件的拟在我国率先上市使用、运用现代科学技术结合我国传统优势项目和特色植物资源研发等新原料，实施提前介入、全程指导，提升新原料研发质量和应用的速度；对符合上述条件的申请注册新原料，以及使用上述新原料的特殊化妆品，设置专门审评通道，优先审评，加速新原料和产品上市。

四、加强对新原料技术指导和沟通交流

加快制定新原料命名等系列研究相关技术指导原则，及时发布共性问题技术问答，加强新技术、新方法的应用研究和技术指导。进一步优化完善化妆品新原料沟通交流工作机制，加强注册备案前和审评核查中的沟通交流，指导企业规范开展注册备案工作。加强国家化妆品审评部门与省级药监部门的技术交流和联动配合，选择具备一定条件和能力

ChemLinked Team, REACH24H Consulting Group

Website: <http://www.chemlinked.com> | Email: contact@chemlinked.com

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