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Provisions for Management of New Cosmetic Ingredient Registration and Notification Dossiers

化妆品新原料注册备案资料管理规定

National Medical Products Administration

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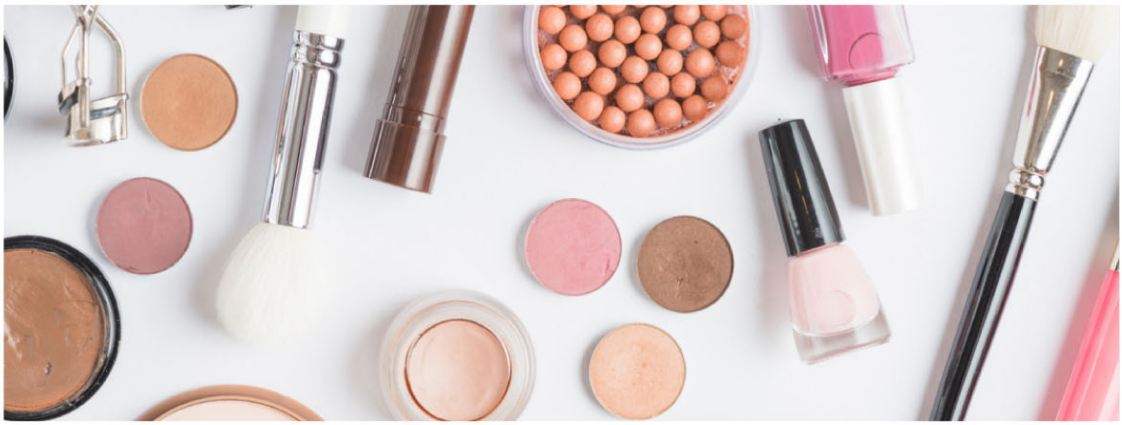

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Attachment

Provisions for Management of New Cosmetic Ingredient Registration and Notification Dossiers

Article 1 For the purpose of standardizing the administration of new cosmetic ingredient registration and notification, ensuring the quality and safety of cosmetics, these Provisions are formulated in accordance with the requirements of "Cosmetic Supervision and Administration Regulations (CSAR)" and "Administrative Measures on Cosmetics Registration and Notification".

Article 2 The documents submitted by the registrant and notifier of new cosmetic ingredient at the time of applying for registration or notification of the new cosmetic ingredient shall meet the requirements of these Provisions.

Article 3 The registration and notification documents of new cosmetic ingredient shall be based on scientific research, and objectively and accurately describe the traits, characteristics and safety use requirements of the new ingredient.

The registrant, notifier or domestic responsible person of new cosmetic ingredient shall submit the registration and notification documents of new cosmetic ingredient as required, and be responsible for the legality, authenticity, accuracy, completeness and traceability of the documents submitted.

Article 4 The registration and notification documents of new cosmetic ingredient shall use standardized Chinese characters published by the State. Except registered trademarks, website addresses, patent names, names and addresses of overseas enterprises, *etc*., which must use other languages, as well as English abbreviations that have been used in China's regulations, all other texts shall be translated into Chinese in a complete and standardized way, and the original text shall be attached to the corresponding translation.

Article 5 The registration and notification documents of new cosmetic ingredient shall comply with the relevant national laws and regulations on the use of signature and seal, be with complete signature and seal, and have legal effect. If overseas enterprises and other organizations do not use official seals, the documents shall be signed by the legal representative or authorized signatory. In case of authorized signature, the original authorization letter and the original notarial certificate shall be submitted. The authorization letter shall specify the matters and scope of the authorized signature.

Except the original of documents issued by the competent government departments or relevant institutions, testing institutions, Notary Public, *etc*., the registration and notification documents shall be stamped with the official seal page by page by the domestic registrant, notifier or domestic responsible person. The user who uses the official seal with the electronic encryption certificate can directly stamp the electronic official seal on the electronic documents.

Article 6 China's legal measurement unit shall be used in the registration and notification documents of new cosmetic ingredient. If other measurement units are used, they shall be converted into China's legal measurement unit; the use of punctuation marks, charts, terminology, *etc*. shall be standardized; references shall be quoted accurately and validly with the source indicated to ensure valid traceability.

Article 7 The main text in the registration and notification documents of new cosmetic ingredient shall be black, and the contents shall be easy to identify. Appropriate line spacing and page margins shall be set to ensure that no text information is lost during printing or binding.

The paper documents for registration and notification shall use the international standard A4 size paper with complete and clear contents, which shall not be altered. The carrier and writing materials of paper documents shall meet the durability requirements.

Article 8 The registrant, notifier or domestic responsible person of new cosmetic ingredient shall apply for registration or notification through an information service platform for the registration and notification of new cosmetic ingredient (hereinafter referred to as the information service platform) as prescribed, and electronic version of the registration and notification documents uploaded to the information service platform shall be consistent with the paper version.

Article 9 The registrant and notifier of new cosmetic ingredient shall fill in the following information through the information service platform to register user information before applying for new ingredient registration or notification.

(I) Information of registrant and notifier of new cosmetic ingredient;

(II) Safety risk monitoring and evaluation system overview of registrant and notifier of new cosmetic ingredient (see Annex 1 for the template);

(III) If the registrant and notifier of new cosmetic ingredient are of overseas ones, the domestic responsible person shall fill in the information, and submit the original authorization letter of the domestic responsible person and the original notarial certificate.

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附件

化妆品新原料注册备案资料管理规定

第一条 为规范化妆品新原料注册和备案管理工作，保证化妆品质量安全，根据《化妆品监督管理条例》《化妆品注册备案管理办法》，制定本规定。

第二条 化妆品新原料注册人、备案人申请化妆品新原料注册或者进行备案时提交的资料，应当符合本规定要求。

第三条 化妆品新原料注册和备案资料应当以科学研究为基础，客观、准确地描述新原料的性状、特征和安全使用要求。

化妆品新原料注册人、备案人或境内责任人应当按要求提交化妆品新原料注册和备案资料，并对所提交资料的合法性、真实性、准确性、完整性和可追溯性负责。

第四条 化妆品新原料注册和备案资料应当使用国家公布的规范汉字。除注册商标、网址、专利名称、境外企业的名称和地址等必须使用的其他文字，以及我国法规文件中使用的英文缩写简称等外，所有使用其他文字的资料均应当完整、规范地翻译为中文，并将原文附在相应的译文之后。

第五条 化妆品新原料注册和备案资料的签章应当符合我国相关法律法规规定，确保签章齐全，具有法律效力。境外企业及其他组织不使用公章的，应当由法定代表人或者授权签字人签字。授权委托签字的，应当提交授权委托书原件及其公证书原件，授权委托书中应当写明授权签字的事项和范围。

除政府主管部门或者有关机构、检验检测机构、公证机关等出具的资料原件外，注册和备案资料均应当由境内注册人、备案人或者境内责任人逐页加盖公章。用户使用带有电子加密证书公章的，可直接在电子资料上加盖电子公章。

第六条 化妆品新原料注册和备案资料应当使用我国法定计量单位，使用其他计量单位的，应当折算为我国法定计量单位；应当规范使用标点符号、图表、术语等；参考文献引用应当准确有效，标明出处，确保有效溯源。

第七条 化妆品新原料注册和备案资料中文本主体文字颜色应当为黑色，内容易于辨认，设置合适的行间距和页面边距，确保在打印或者装订中不丢失文本信息。

注册和备案纸质资料应当使用国际标准 A4 型规格纸张，内容完整清晰、不得涂改。纸质文件资料的载体和书写材料应当符合耐久性的要求。

第八条 化妆品新原料注册人、备案人或境内责任人应当按照规定，通过化妆品新原料注册备案信息服务平台（以下简称信息服务平台）申请注册或进行备案，信息服务平台中填写、上传的注册和备案资料电子版应当与纸质版保持一致。

第九条 化妆品新原料注册人、备案人在申报新原料注册或进行新原料备案前，应当通过信息服务平台，填报以下信息，进行用户信息登记：

（一）化妆品新原料注册人、备案人信息；

（二）化妆品新原料注册人、备案人安全风险监测和评价体系概述（样例见附 1）；

（三）化妆品新原料注册人、备案人为境外的，应当由境内责任人填报信息，同时提交境内责任人授权书及其公证书的原件。

同一境内企业同时具有化妆品新原料注册人、备案人或境内责任人等多重身份的，或经授权作为多个境外化妆品新原料注册人、备案人的境内责任人的，可一次性提交全部相关资料后取得相应的用户权限。已有用户可以根据实际情况补充提供相关资料，增加用户权限。

第十条 化妆品新原料注册人、备案人或境内责任人的以下信息资料发生变化时，应当进行更新，确保信息服务平台中的相关信息资料真实准确：

（一）化妆品新原料注册人、备案人或境内责任人的法定代表人、联系方式等信息发生变化时，用户应当在信息服务平台上及时自行更新；

（二）化妆品新原料注册人、备案人或境内责任人的其他基本信息、新原料安全风险监测和评价体系概述、境内责任人的授权范围和授权期限发生变化的，应当提交化妆品新原料注册人、备案人信息更新表（样例见附 2），并按要求提交相关资料后完成相关信息资料的更新。

其中，境外注册人、备案人名称、地址发生变化的，应当提供由所在国（地区）政府主管部门或者有关机构出具的主体未发生变化的相关证明文件原件，无法提交原件的，应当提供由中国公证机关公证的或由我国使（领）馆确认的复印件；境内责任人名称、地址发生改变的，应当提供我国政府主管部门或者有关机构出具的主体未发生变化的相关证明文件原件。

境内责任人授权范围改变的，新授权范围应当包括原授权范围；仅进行授权期限更新的，授权书其他内容不得改变。

境内责任人变更的，应当提交拟变更境内责任人承担原境内责任人相关各项责任的承诺书，同时提交原境内责任人关于更换境内责任人的知情同意书或者能够证明境内责任人发生变更的已生效法律判决文书。