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Instructions for Toothpaste Notification Dossiers (Draft for Comments)

牙膏备案资料规范（征求意见稿）

National Medical Products Administration

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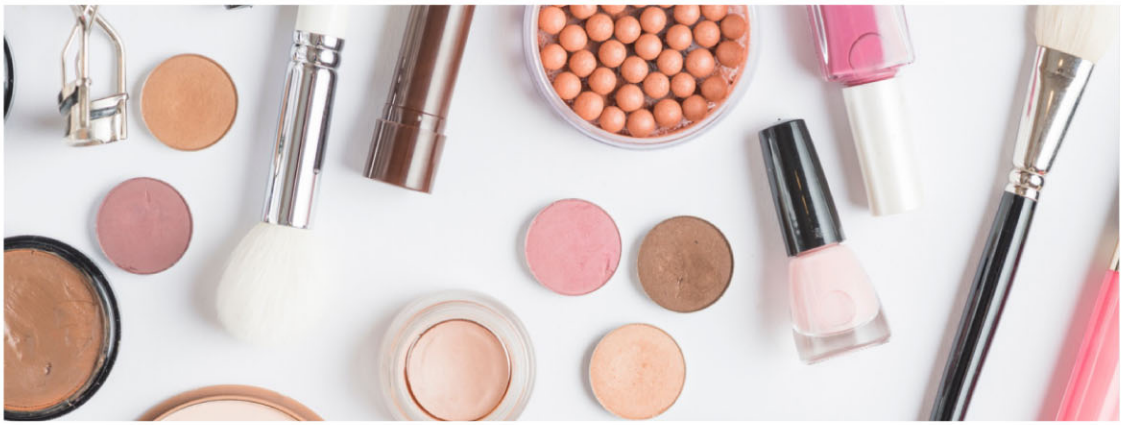

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Instructions for Toothpaste Notification Dossiers

(Draft for Comments)

Chapter I General Rules

Article 1 Overview For the purpose of regulating the administration of toothpaste notification, ensuring the standardized submission of various toothpaste notification documents, these Instructions are hereby formulated in accordance with the requirements of "*Cosmetic Supervision and Administration Regulations*" (CSAR) and "*Administrative Measures on Toothpaste*" and other relevant laws and regulations.

Article 2 Application Scope The submission of documents for notification of toothpastes that are produced and operated within the territory of the People's Republic of China shall meet the requirements of these Instructions.

Article 3 General Requirements The toothpaste notifier shall follow the principles of risk administration, based on scientific research, be responsible for the authenticity, legality, and completeness of the submitted notification documents, and bear corresponding legal responsibilities. The overseas toothpaste notifiers shall supervise the notification of domestic responsible persons.

Article 4 Requirements for Text and Translation The toothpaste notification documents shall use standardized Chinese characters published by the State. Except for registered trademarks, website addresses, patent names, names and addresses of overseas enterprises, *etc.*, which must use other languages, all other texts shall be fully and normatively translated into Chinese, and the original texts shall be attached following the corresponding translation.

Article 5 Requirements for Signature and Seal The toothpaste notification documents shall comply with the relevant national provisions on the use of seals, be with complete signatures and seals, and have legal effect. According to provisions, if overseas enterprises and other organizations do not use the official seal, the documents shall be signed by the legal representative or the person in charge of the enterprise (other organization).

Except for the document originals issued by the competent government departments or relevant institutions, notification testing institutions, notary publics, *etc.*, the notification documents shall be stamped with the official seal page by page by the domestic 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 Requirements for Standardization China's legal measurement units shall be used in the toothpaste notification documents. If other measurement units are used, they shall be converted into China's legal measurement units; references shall be cited accurately, and the citation format shall comply with the relevant national standards of China; the use of punctuation marks, diagrams, terminology, *etc*. shall be standardized to ensure that all the contents of the documents are accurate and standardized.

Article 7 Requirements for Consistency The contents of the same item in the toothpaste notification documents shall be consistent; if there are relevant certification documents, the item contents shall be accordant with the those included in such certification documents.

Article 8 Requirements for Format and Display The main text in the toothpaste notification documents 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.

Article 9 Requirements for Paper and Printing For the paper documents of toothpaste notification, the internationally standard A4 size paper shall be used, with contents complete and clear, which shall not be altered. If larger size paper is needed for the unfolding pictures of toothpaste packaging, other sizes of paper can be used to ensure that it is properly placed in the A4 size documents. The carrier and writing materials of paper documents shall meet the durability requirements.

Chapter II Requirements for User Information Related Documents

Section I Document Items and Requirements

Article 10 User Information Related Document Items When handling toothpaste notification for the first time, the following user information related documents shall be submitted:

(I) Notifier Information Form (see Attachment 4) and the resume of the person in charge of quality and safety;

(II)Overview of Quality Management System of Notifier (see Attachment 5);

(III) Overview of Adverse Reaction Monitoring and Evaluation System of Notifier (see

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

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+ Cosmetic Product Notification Portal (CPNP)
+ 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)
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附件 1

牙膏备案资料规范
（征求意见稿）

第一章 总则

第一条（概述）为规范牙膏备案管理工作，保证牙膏备案各项资料的规范提交，依据《化妆品监督管理条例》《牙膏监督管理办法》等有关法律法规要求，制定本规范。

第二条（适用范围）在中华人民共和国境内生产经营的牙膏备案时提交的资料，应当符合本规范要求。

第三条（总体要求）牙膏备案人应当遵循风险管理的原则，以科学研究为基础，对提交的备案资料的真实性、合法性、完整性负责，并且承担相应的法律责任。境外牙膏备案人应当对境内责任人的备案工作进行监督。

第四条（文字和翻译要求）牙膏备案资料应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其他文字的，所有其他文字均应完整、规范地翻译为中文，并将原文附在相应的译文之后。

第五条（签章要求）牙膏备案资料应当符合国家有关用章规定，签章齐全，具有法律效力。按照规定，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企业（其他组织）负责人签字。

除政府主管部门或者有关机构、备案检验机构、公证机关等出具的资料原件外，备案资料均应由境内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的公章的，可直接在电子资料上加盖电子公章。

第六条（规范性要求）牙膏备案资料中应当使用我国法定计量单位，使用其他计量单位时，应当折算为我国法定计量单位；应当准确引用参考文献，引用格式应当符合我国相关国家标准；应当规范使用标点符号、图表、术语等，保证资料内容准确规范。

第七条（一致性要求）牙膏备案资料中，出现的同项内容应当保持前后一致；有相关证明文件的，应当与证明文件中所载内容一致。

第八条（格式和显示要求）牙膏备案文本资料中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。

第九条（纸张和打印要求）牙膏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。牙膏的包装展开图片等确需更大尺寸纸张的，可使用其他规格纸张，确保妥善置于 A4 规格资料内。纸质文件资料的载体和书写材料应当符合耐久性的要求。

第二章 用户信息相关资料要求

第一节 资料项目及要求

第十条（用户信息相关资料项目）首次办理牙膏备案时，应当提交以下用户信息相关资料：

（一）备案人信息表（附件 4）及质量安全负责人简历；

（二）备案人质量管理体系概述（附件 5）；

（三）备案人不良反应监测和评价体系概述（附件 6）；

（四）境外备案人应当提交境内责任人信息表（附件 7）；

（五）境外备案人应当提交境内责任人授权书原件（式样见附件 8）及其公证书原件；

（六）备案人有自主生产或者委托境外生产企业生产的，应当提交生产企业信息表（附件 9）和质量安全负责人简历，一次性填报已有生产企业及其信息。生产企业为境外的，应当提交境外生产规范证明资料原件。

我国境内仅从事受托生产的企业，应当提交第（六）项中的生产企业信息表和质量安全负责人简历，以便关联确认委托生产关系。

具有境内备案人、境内责任人、生产企业等多重身份的，或者同一境内责任人对应多个境外备案人的，可以一次性提交全部相关资料，审核通过后获得相应的用户权限。已有用户可以根据情况补充提供相关资料，增加用户权限。

第十一条（质量安全负责人简历要求）质量安全负责人的简历应当包括质量安全负责人的教育背景、工作经历以及证明其符合相关要求的其他内容。

第十二条（质量管理体系概述要求）质量管理体系概述是对备案人质量管理控制能力和过程的总结描述，应当如实客观地反映实际情况。语言应当简明扼要，体现出质量控制关键点设置和日常执行管理要求。

备案人同时存在自主生产和委托生产的，应当分别提交相应版本的质量管理体系概述。