Personal Care Products Council

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Re: Comments on the Opinions on Deepening Reform of Cosmetic Administration and Promoting High-Quality Development of the Industry (Draft for Comment)
主题：关于《关于深化化妆品监管改革促进产业高质量发展的意见（征求意见稿）》的意见

Respected National Medical Products Administration ("NMPA"):
尊敬的国家药品监督管理局（下称"贵局"）：

The Personal Care Products Council ("PCPC") is pleased to have the opportunity to comment on NMPA's Opinions on Deepening Reform of Cosmetic Administration and Promoting High-Quality Development of the Industry (Draft for Comment) ("Opinions").[1]
美国个人护理产品协会（下称"PCPC"）很荣幸就贵局发布征求意见的《关于深化化妆品监管改革促进产业高质量发展的意见（征求意见稿）》（下称"意见"）提交以下意见。[2]

[1] PCPC represents over 600 companies, including global and U.S.-based manufacturers and distributors of finished products, as well as suppliers of ingredients, raw materials, packaging, and other services used in the production and marketing of finished personal care products. PCPC advises and represents our members on legal, regulatory, scientific, and international trade matters affecting our industry globally. We work closely with our members to develop industry technical guidance documents and best practices and to achieve industry-wide consensus positions on policy issues.
[2] PCPC 代表 600 多家会员公司，其中包括全球及美国的最终产品制造商和经销商以及用于个人护理产品生产和营销的成分、原材料、包装及其他服务的供应商。PCPC 就影响我们行业的全球法律、监管、科学及国际贸易事项为我们的会员提供咨询和代理服务。我们与会员紧密合作，制订行业技术指引和最佳惯例，实现全行业在政策方面的共识。

PCPC is encouraged to see the Opinions' proposals to increase stakeholder participation in the regulatory process. PCPC also strongly supports NMPA's commitment to make the record-filing and registration processes for cosmetic products and cosmetic ingredients more efficient, and to harmonize the regulatory framework with international standards. Consistent with these principles, we would like to offer the following additional suggestions, organized based on the sections of the Opinions. We look forward to the opportunity to comment on additional regulations and rules as those drafts emerge to implement the Opinions.

PCPC深受鼓舞地注意到《意见》提出的增加利益相关方参与监管过程的建议。PCPC 还强烈支持贵局致力于提高化妆品和化妆品原料备案及注册流程效率，并将监管框架与国际标准接轨。基于这些原则，我们希望提供以下额外建议，这些建议对照《意见》的相应条款编制。我们期待有机会对未来出台的实施《意见》的其他行政法规和规章草案提出意。

I. Increase Support for Innovation in the Industry

加大产业创新支持力度

PCPC strongly agrees with the Opinions' proposal to create a regular and widely available mechanism for applicants to consult with cosmetic reviewers at the National Institutes for Food and Drug Control or at the provincial-level, if the review is delegated.[3] The opportunity for a consultation should be readily available to applicants for products and ingredients. In addition, to protect business confidential information and trade secrets, the identity of the product or ingredient with which the review is associated and reviewers' feedback as part of the consultation should remain confidential.

PCPC 十分赞同《意见》提出的建立常规且广泛可用的咨询机制的建议，以便申请人能够在中国食品药品检定研究院或省级部门（如果审评权被下放）向化妆品审评员进行咨询。[4]产品和原料的申请人应该能够随时获得咨询机会。此外，为了保护商业保密信息和商业秘密，审评所涉及的产品或原料以及审评员在咨询中的反馈应予以保密。

We are supportive of the Opinions' proposal to remove the requirement for the certificate of free sale requirement (i.e., proof of foreign approval) for cosmetics that are first marketed in China or simultaneously in China along other jurisdictions.[5] However, we encourage NMPA to remove this requirement for all cosmetic products, regardless of whether China is the first jurisdiction or among the first jurisdictions in which the product is launched. Because NMPA's record-filing or registration process for general and special cosmetics already contains rigorous safety and effectiveness requirements, applicants should not need to supply foreign approval to demonstrate safety or efficacy.

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[3] Opinions, Articles 1 & 7.
[4] 《意见》，第1条及第7条。
[5] Opinions, Article 2.

我们支持《意见》提出的以下建议，对于在中国首发上市或者在中国以及其他国家（地区）同步上市的化妆品，免于提交在生产国（地区）已上市销售的证明文件（即外国批准证明）。[6]然而，我们希望贵局对所有化妆品产品取消这一要求，无论中国是否为首个或首批上市地区。因为贵局对一般和特殊化妆品的备案或注册程序已包含严格的安全性和有效性要求，申请人无需提供外国批准即可证明产品的安全性或有效性。

Furthermore, even if the requirement of proof of foreign approval is not waived for all cosmetics, it should be at least waived for innovative products whose new ingredients have to be record-filed or registered in China, prior to the submission of the product application. Because of potential delays associated with this separate application for new ingredients, products with new ingredients should be treated as new-to-the-world as of the time of the ingredient submission, even though the product application may have been submitted in other jurisdictions prior to the product application in China. And these innovative products should enjoy the waiver of foreign approval requirement.

此外，即使不对所有化妆品免除提供外国批准的要求，也至少应对含有须在产品申请提交前进行备案或注册的新原料创新产品免除该要求。由于新原料单独申请可能带来的潜在延误，对于含有新原料的产品，应按原料在中国的备案或注册提交之日计算是否为世界首发，即便该产品申请在中国产品申请之前可能已在其他司法辖区提交。在这种情况下，这些创新产品应享受免除国外批准要求的待遇。

The Opinions also seek to establish regulations through which holders of cosmetic record-filings could conduct simple mixing, blending, or re-packaging in retail establishments.[7] We suggest NMPA consider expanding this flexibility to special cosmetics. In addition, product registrations and record-filings should allow variations, e.g., in colors, such that personalization could be provided without the need for obtaining multiple record-filings or registrations to cover each possible variation.

《意见》还旨在通过制定相关规定，使化妆品备案持有人能够在经营场所进行简易的调配或分装。[8]我们建议贵局考虑将这种灵活处理扩展至特殊化妆品。此外，产品注册和备案应当允许存在差异，例如颜色上的差异，以便在不需要为每种可能的变体单独办理备案或注册的情况下提供个性化服务。

II. Increase Efficiency in the Registration and Record-Filing Process

[6] 《意见》，第2条。
[7] Opinions, Article 5.
[8] 《意见》，第5条。

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提高注册和备案流程的效率

For both safety and efficacy claims, we suggest NMPA remove the requirement that the cosmetics products be of the "same brand" for them to be eligible to share testing data,.[9] Eligibility to share safety and efficacy data should be based on the similarity of the formula, and should not require the manufacturer to market the products under the same brand. Permission from the rights holder should be required if the two products are not from the same applicant.

关于安全性和功效宣称，我们建议贵局取消化妆品产品必须为"同一品牌"才能共享试验数据的要求。[10]共享安全性和功效数据的资格应基于配方的相似性，而不应要求生产企业以同一品牌销售产品。若申请共享数据的产品并非来自于同一申请人，则应当在征得数据拥有者的同意后才能共享。

We are encouraged to see the Opinions' suggestion to afford companies greater flexibility to determine the tests and standards according to which their products' claims are evaluated.[11] In providing this flexibility, future regulations should permit applicants to select not only domestic but also internationally accepted methods to support a product's claims.

我们很高兴看到《意见》提出的给予企业更大的灵活性来确定评价其产品功效宣称的试验和标准。[12]未来实施这一灵活性的法规应当允许申请人不仅可以选择国内认可的方法，还可以选择国际公认的方法来支持产品的功效宣称。

Furthermore, NMPA should allow applicants for imported general cosmetics to use their own laboratories, as opposed to using National Institutes for Food and Drug Control's laboratories, to produce test reports for registration. Currently, this flexibility is only granted to domestic companies, and manufacturers of products produced overseas should be able to enjoy the same benefit. Indeed, manufacturers of medical devices, which are more strictly regulated, have been able to utilize their own laboratories for registration testing, regardless of whether the manufacturer is domestic or foreign.[13]

此外，贵局应当允许进口普通化妆品的申请人使用其自有实验室，而不是使用食品药品检定研究院的实验室，来出具注册所需的检验报告。目前，这种灵活性仅给予境内公司，但是境外产品生产企业也应当享有同等待遇。事实上，无论是境内还是境外医疗器械生产企业（其受到更为严格的监管）都被准许使用其自有实验室进行注册所需的检验。[14]

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[9] Opinions, Articles 8 & 11.
[10] 《意见》，第8条及第11条。
[11] Opinions, Article 11.
[12] 《意见》，第11条。
[13] Regulation on the Supervision and Administration of Medical Devices, Article 14 (2021).
[14] 《医疗器械监督管理条例》，第14条（2021）。

We also suggest NMPA allow minor changes in raw material composition to be notified, without the need for review by NMPA or local medical products administrations. For example, a supplier of a raw material may make a process change that results in minor adjustments in the percentages of certain ingredients and that does not affect product safety, effectiveness or quality. Currently, Article 42 of the *Provisions for Management of Cosmetic Registration and Record-Filing Dossiers* only specifies required processes for a change in the raw material supplier where the ingredients in the raw materials have not changed, and for a change in the "trace stabilizer, antioxidant, preservative, and other ingredient" in the raw material to ensure its quality. It is unclear what process applies for minor changes in the percentages of ingredients in a raw material whereby the supplier and the ingredients of the raw material do not change. For this type of change, to avoid unnecessary burdens in the regulatory process and given the low risk level, we suggest NMPA specify that only a simple notification is required, and the manufacturer of the cosmetic can proceed with the change as long as NMPA does not object to the change within a reasonable period of time. PCPC would welcome the opportunity to participate in a working group with representatives from NMPA, NIFDC, and other international and domestic organizations to consider proposals for policy on minor change notifications.

我们还建议贵局对原材料的成分配比的微小变化仅要求通知，而无需贵局或地方药监部门的审核。例如，原料供应商可能进行工艺变更，导致某些成分的比例略有调整，但不会影响产品的安全性、有效性或质量。目前，《化妆品注册备案资料管理规定》第42条仅规定了在原料的成分未发生变化的情况下原料生产商变更以及为了保证原料质量而更换原料中"微量稳定剂、抗氧化剂、防腐剂等成分"的必需流程。然而，对于原料成分比例的微小变化且供应商及原料成分均未改变的情况，应适用何种流程仍不明确。针对此类变更，为避免在监管过程中增加不必要的负担，并鉴于其低风险，我们建议贵局明确规定，仅需进行简单通知，并且化妆品生产企业在贵局在合理时间内未提出异议的情况下，可以进行该变更。PCPC欢迎参与到由国家药品监督管理局、食品药品检定研究院和其他国内外组织的代表组成的工作小组的机会，来讨论有关微小变更通知的提案。

III. Harmonize with International Standards
与国际标准接轨

We are encouraged to see NMPA's commitment to "promote the alignment of domestic standards and international standards."[15] We urge NMPA to harmonize its rules governing cosmetic quality with international standards, particularly ISO rules. As such, further regulations should make it clear that overseas manufacturers may comply with International Standards Organization ("ISO") standards as a means of meeting China's quality requirements. In this respect, samples

[15] Opinions, Article 22.

for imported products should be permitted to be retained overseas and made available upon request. Similarly, any overseas inspection rules, which should be in place *prior* to conducting any overseas inspections, should also make it clear that ISO reliance is permitted as a means of demonstrating compliance with China's requirements.

我们很高兴看到贵局承诺"推动国内标准与国际标准接轨"。[16]我们恳请贵局将化妆品质量管理规则与国际标准（特别是ISO标准）进行接轨。因此，进一步的法规应明确规定，境外生产企业可依照国际标准化组织（ISO）标准作为符合中国质量要求的方式。在这方面，进口产品的样品应允许保留在海外，并在需要时提供。同样，任何海外检查规则（其应该在进行任何海外检查之前已制定）也应明确允许依赖ISO标准作为证明符合中国要求的方式。

We are encouraged to see the Opinions' proposal to "accelerate and promote the exemption for animal testing."[17] We welcome China's efforts in continuing to permit applicants to rely upon alternatives to animal testing, particularly when those tests are internationally accepted. However, to make the animal testing exemption applicable to a broader set of applicants, we suggest NMPA remove the requirement for a manufacturing quality certificate for companies to qualify for an animal testing exemption. China's requirement for a full safety assessment, which has been in effect since May 2025,[18] and its evaluation of both products and raw materials for safety is sufficient to ensure safety without animal testing. The current requirement for a manufacturing quality certificate is an administrative burden that should be removed. The removal of the manufacturing quality certificate would allow applicants to focus their resources on alternative testing methods, as the Opinions suggest. Additionally, the Opinions state that the implementation of animal testing exemptions should be gradual, "starting with lower-risk products such as perms and non-oxidative hair dyes."[19] We suggest NMPA add sunscreen to the list of products to first receive an exemption from animal testing, because sunscreen products have had sufficient historical safety data and enjoy animal testing exemptions in other jurisdictions.[20]

我们深受鼓舞地注意到，《意见》提出"加快推进动物试验减免"。[21]我们赞赏中国在继续允许申请人依赖替代动物试验方法方面的努力，尤其是那些在国际上被认可的替代试验方法。然而，为了让动物试验减免适用于更广泛的申请人，我们建议贵局取消企业提供生产

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[16] 《意见》，第22条。
[17] Opinions, Article 23.
[18] NMPA Announcement on the Issuance of Several Measures to Optimize the Management of Cosmetics Safety Assessment (Apr. 22, 2024).
[19] Opinions, Article 23.
[20] FDA, *FDA Encourages Development of New, Reliable Alternatives to Animal Testing in Sunscreen* (last updated Sept. 30, 2025).
[21] 《意见》，第23条。

质量管理体系相关资质认证才能获得动物试验减免的规定。中国自2025年5月起实施的全面安全评估要求[22]及其对产品和原材料的安全性评估已足以在无需动物试验的情况下确保安全性。当前对生产质量管理体系相关资质认证的要求是一种行政负担，应予以取消。取消生产质量管理体系相关资质认证的要求将使申请人能够将资源集中于替代性试验方法，如《意见》所建议的那样。此外，《意见》提到，应"从烫发、非氧化型染发等风险较低产品着手"[23]， 逐步推行动物试验豁免。我们建议贵局将防晒产品加入首批着手豁免动物试验的名单，因为防晒产品已经有充足的历史安全性数据，并且在其他地区享有动物试验豁免。[24]

We applaud NMPA's commitment to facilitate the approval of ingredients that have been scientifically evaluated by international authoritative organizations and have a history of safe use abroad.[25] For such ingredients, we urge NMPA to consider basing the approval on existing standards in foreign jurisdictions. If the applicant can demonstrate that the ingredient has already been approved or is the subject of existing standards or guidance overseas, NMPA should grant record-filing or registration of the ingredient in China on that basis without requiring additional testing.

我们赞赏贵局致力于加快对那些已经被国际权威机构科学评价且在国外具有安全使用历史的原料的审批。[26]对于此类原料，我们恳请贵局考虑基于外国司法辖区现有标准来进行审批。如果申请人能够证明该原料已经在海外获得批准，或属于海外现有标准或指南的范畴，贵局应在此基础上在中国予以备案或注册，而不要求额外试验。

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PCPC is grateful for the opportunity to provide comments on the Opinions. As the NMPA implements the principles in the Opinions, we look forward to seeing drafts of revisions to the Regulation on the Supervision and Administration of Cosmetics and implementing rules and measures and providing comments on them. Should you have any questions about these comments we would be happy to meet and discuss further. Please do not hesitate to reach out to me at ObermannN@personalcarecouncil.org.

[22] 国家药品监督管理局《国家药监局关于发布优化化妆品安全评估管理若干措施的公告》（2024年4月22日）。
[23] 《意见》，第23条。
[24] FDA，《FDA 鼓励开发新的、可靠的防晒产品替代动物试验方法》（最近更新于2025年9月30日）
[25] Opinions, Article 24.
[26] 《意见》，第24条。

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PCPC 感谢有机会就《意见》提供意见。在贵局实施《意见》中的原则时，我们期待能够看到《化妆品监督管理条例》的修订草案及其实施细则和办法的草案，并对其提供意见。如果您对这些意见有任何疑问，我们非常乐意会面进一步讨论。如需联系，请随时发送邮件至 ObermannN@personalcarecouncil.org 。

Sincerely,
此致，

Natalie Obermann
Vice President Global Strategies
全球战略副总裁