



Re: 关于英国政府颁发《化妆品良好生产规范证书》的说明

尊敬的国家药品监督管理局,

作为英国商业、能源和产业战略部 (Department for Business, Energy & Industrial Strategy, 简称BEIS) 的下属部门, 产品安全与标准办公室 (Office of Product Safety & Standard, 简称OPSS) 是英国主管包括化妆品在内消费品的国家监管部门, 即英国化妆品主管部门。

自《化妆品监督管理条例》(CSAR) 及相关法规和导则于2021年5月1日生效以来, 英国商业、能源和产业战略部产品安全与标准办公室 (BEIS-OPSS) 建立了证书颁发体系, 为英国境内生产化妆品的品牌和企业提供符合《良好生产规范》的证明文件, 在审核通过的前提下, 英国政府即颁发《良好生产规范证书》, 以便于向中国出口。

根据《化妆品注册备案资料管理规定》第三十三条, 普通化妆品免于提交毒理学试验报告的前提之一是“生产企业已取得所在国(地区)政府主管部门出具的生产质量管理体系相关资质认证”。英国商业、能源和产业战略部产品安全与标准办公室 (BEIS-OPSS) 与英国国际贸易部 (Department for International Trade, 简称DIT) 已签署关于颁发英国《化妆品良好生产规范证书》的谅解备忘录, 确认英国商业、能源和产业战略部产品安全与标准办公室 (BEIS-OPSS) 授权英国国际贸易部代为颁发《化妆品良好生产规范证书》。

产品安全与标准办公室审核小组与英国国际贸易部进口许可证处 (Import Licensing Branch of DIT, 简称ILB) 持续监测证书颁发体系, 已确保颁发流程准确高质。因此, 英国政府收到的所有《化妆品良好生产规范证书》的申请均由英国商业、能源和产业战略部产品安全和标准办公室 (BEIS-OPSS) 监督并授权英国国际贸易部进口许可证处 (ILB) 颁发。

特此说明。

Graham Russell MBE
CEO, Office for Product Safety and Standards

英国商业、能源和产业战略部

22nd October 2021

Re: Clarifications Regarding UK Government's Good Manufacturing Practice Certification for Cosmetics

To: National Medical Products Administration,

As part of the UK Department for Business, Energy and Industrial Strategy (BEIS), the Office for Product Safety and Standards (OPSS) is the UK national regulator for consumer products including cosmetics. BEIS-OPSS is thus the UK competent authority responsible for the supervision of cosmetic products.

Since the overarching Cosmetic Supervision and Administration Regulation (CSAR) and its implementing texts came into force on 1 May 2021, BEIS-OPSS has implemented a system whereby brands and companies manufacturing cosmetics in the UK can provide evidence of compliance with Good Manufacturing Practices (GMP). On approval, a GMP certificate is issued by the UK Government for export to China.

The CSAR Instructions for Cosmetic Notification and Registration Dossiers, Article 33.2, requires the certificates to be issued by "the responsible government department of the country/region where [the manufacturers] are based". A Memorandum of Understanding (MoU) has been signed between BEIS-OPSS and the UK Department for International Trade (DIT), which outlines the UK GMP certification issuing arrangement. Through this MoU, BEIS-OPSS has authorised DIT to issue such GMP certificates.

The Review Team within the Office for Product Safety and Standards continues to review this arrangement with the Import Licensing Branch of DIT to ensure quality and accuracy of the issuing is indefinitely sustained. Applications for UK Government issued GMP certificates are thus overseen by BEIS-OPSS and issued by the DIT Import Licensing Branch (DIT-ILB) on behalf of, and as authorised by, BEIS-OPSS.

Yours sincerely,



Graham Russell MBE

CEO, Office for Product Safety and Standards

Department for Business, Energy & Industrial Strategy