# 关于华润博雅生物制药集团股份有限公司 GMP 检查情况的说明

# Clarification on GMP license of China Resources Boya Bio-pharmaceutical Group Co., Ltd.

2018 年 09 月 03 日，经江西省食品药品监督管理局审查，博雅生物制药集团股份有限公司血液制品车间，符合中华人民共和国《药品生产质量管理管理规范》要求，核发药品 GMP 证书。证书编号：JX20170025，有效期至 2022 年 07 月 10 日。

On March 9, 2017, after the examination of Jiang Xi Medical Products Administration of China, the plasma-derived product work shop of Boya Bio-Pharmaceuticals Group Co., Ltd. met the requirements of Good Manufacturing Practices of Medical Products of the People's Republic of China, and issued the GMP certificate for drugs. The certificate number is: JX20170025 with valid period until July 10, 2022.

按照新药品管理法的规定，2019.12.01 后，取消药品的 GMP 认证，也不再受理企业的 GMP 认证申请和发放 GMP 证书。我公司 GMP 证书到期日为 2022 年 07 月 10 日后，所以按照新药品管理法的要求我公司未申请新的 GMP 认证。

According to the provisions of the new Drug Administration Law of the People's Republic of China, since December 1, 2019, the GMP certification of drugs has been canceled and enterprise's GMP certification applications and GMP certificates shall no longer be accepted. The GMP certificate of our company expired on July 10, 2022, so our company has not applied for new GMP certification according to the requirements of the new drug administration law.

江西省局及抚州市局按照法规要求，对我司进行了日常的现场监督检查，日常监督检查的结果，我公司符合 GMP 规范的要求。

Jiang Xi Medical Products Administration of China and Fu Zhou Administration For Market Regulation both carried out daily on-site supervision and inspection on our company according to the requirements of laws and regulations. As a result of daily supervision and inspection, our company meets the requirements of GMP standards.

华润博雅生物制药集团股份有限公司

China Resources Boya Bio-pharmaceutical Group Co., Ltd.

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