1/0

# 安徽省药品监督管理局

# 药品再注册批准通知书

受 理 号：CYSZ2000541皖　　通知书编号：2020R002979

| | | | |
|---|---|---|---|
| 药品名称 | 药品通用名称： 注射用重组人生长激素<br>英文名/拉丁名： Recombinant Human Growth Hormone for Injection | | |
| 商品名称 | 安苏萌 | | |
| 主要成分 | 重组人生长激素 | | |
| 剂　　型 | 注射剂 | 申请事项 | 境内生产药品再注册 |
| 规　　格 | 10IU/3.33mg/支 | 注册分类 | 治疗用生物制品 |
| 药品注册标准编号 | YBS00032020 | 原药品批准文号 | 国药准字S20093034 |
| 包装规格 | 1支/盒 | 药品有效期 | 24 个月 |
| 审批结论 | 经审查，本品符合《药品注册管理办法》的有关规定，同意再注册。 | | |
| 上市许可持有人 | 名称：安徽安科生物工程（集团）股份有限公司<br>地址：合肥市长江西路669号高新区海关路K-1 | | |
| 生产企业 | 名称：安徽安科生物工程（集团）股份有限公司<br>地址：合肥市长江西路669号高新区海关路K-1 | | |
| 药品批准文号 | 国药准字S20093034 | 药品批准文号有效期 | 至2025-10-14 |
| 主 送 | 安徽安科生物工程（集团）股份有限公司 | | |
| 抄 送 | 合肥市市场监督管理局 | | |
| 备 注 | 建议继续完成国家药品监督管理局药品注册批件（批件号：2020S00065）中要求研究的内容。 | | |

安徽省药品监督管理局

2020年10月15日

Translation:

# ANHUI MEDICAL PRODUCTS ADMINISTRATION

## Notice of approval for drug re-registration

Acceptance number:CYSZ000541WAN Notification number:2020R002979

| | | | |
|---|---|---|---|
| Drug Name | INN: Recombinant Human Growth Hormone for Injection<br>English name / Latin name:Recombinant Human Growth Hormone for Injection | | |
| Trade name | Ansomone | | |
| Active ingredient | Recombinant Human Growth Hormone | | |
| Dosage form | Lyophilized powder injection | Application items | Re-registration of domestic products |
| Specification | 10IU/3.33mg/vial | Registration classification | Therapeutic biological products |
| Drug registration standard number | YBS00032020 | Original drug approval number | GYZZS20093034 |
| Packing specification | 1 vial/box | Validity period of drug | 24 months |
| Conclusion of examination and approval | After examination, this product conforms to the relevant provisions of the measures for the administration of drug registration, and it is agreed to be registered again. | | |
| Marking Authorization Holder | Name: Anhui Anke Biotechnology (Group) Co., Ltd<br>Address: AnkeBio Buildings, 669 West Changjiang Road, Hefei, Anhui, 230088, P.R. China | | |
| Manufacturer | Name: Anhui Anke Biotechnology (Group) Co., Ltd<br>Address: AnkeBio Buildings, 669 West Changjiang Road, Hefei, Anhui, 230088, P.R. China | | |
| Drug approval number | GYZZS20093034 | Period of validity | Until 14/10/2025 |
| Main sending | Anhui Anke Biotechnology (Group) Co., Ltd | | |
| Make a copy for | Hefei market supervision and Administration Bureau | | |
| Note | It is suggested to complete the contents required in the approval document for drug registration of the State Drug Administration (approval document No.: 2020S00065). | | |

ANHUI MEDICAL PRODUCTS ADMINISTRATION

15/10/2020