《关于欧盟人用药物活性物质GMP原则及指南授权法案》的意见：

一、对12中“医药产品的上市许可（活性物质的上市不受上市许可约束）”。建议活性物质的上市也按照药品要求进行上市许可。

二、对13中“条款4（1）（依照GMP）-涉及到生产许可时：活性物质的生产不受许可约束”。建议活性物质也按照药品要求进行生产许可。

三、建议欧盟对药物活性物质生产企业的药品GMP符合性进行强制性检查，并向企业颁发药品GMP符合性证明文件。

中国国家食品药品监督管理局

2012-4-6

English Translation:

Comments on DELEGATED ACT ON THE PRINCIPLES AND GUIDELINES OF GOOD MANUFACTURING PRACTICE FOR ACTIVE SUBSTANCES IN MEDICINAL PRODUCTS FOR HUMAN USE

1. “12 – Marketing authorizations for medicinal products (the placing on the market of active substances per se is not subject to a marketing

authorization)”

We suggest that the placing on the market of active substances should be subject to a marketing authorization as that for drugs.

2. “13-- Article 4(1) ('Conformity with good manufacturing practice') – insofar as it relates to the manufacturing authorization: The manufacturing of active substances is not subject to an authorization.”

   We suggest that active substances should be subject to manufacturing authorization as that for drugs.

3. We suggest that EU launch compulsory drug GMP inspections to active substances manufacturers and issue relevant proving document to manufacturers complying with drug GMP requirements.

China State Food and Drug Administration