Dear Sir/Madam Conerned,

We are the API manufacturers in Biocause Group in China, i.e. Hubei Granules-Biocause Pharmaceutical Company Ltd., Hubei Biocause Heilen Pharmaceutical Co., Ltd. , and Wuhan Biocause Pharmaceutical Development Co., Ltd.

We have fully read the consultation paper, i.e. DRAFT TEMPLATE FOR THE WRITTEN CONFIRMATION FOR ACTIVE SUBSTANCES IMPORTED INTO THE EUROPEAN UNION FOR MEDICINAL PRODUCTS FOR HUMAN USE PUBLIC CONSULTATION, and respond as follow.

We manufacture the products exporeted to EU wholly according to the good manufacturing practice of European Union and we confirm that the standards of good manufacturing practice and control of the plant are equivalent to those in the Union. We can issue the confirmation by ourselves. But we cannot require the the competent authority to issue such confirmation because the authority has their own working plan, which will not affected by the manufactures. So would you please also inform the SFDA of China to supervise the API manufactures in China by EU GMP, and supply any non-compliance findings to the EU without delay? Then the regulatory authority would be willing to issue the confirmation.

Best regards,

Cheng Sen

Regulatory Affairs

Hubei Biocause