Translation for reference:

SFDA Comments to *Public Consultation on the Draft Template for the Written Confirmation for Active Substances Imported into the EU for Medicinal Products for Human Use*

SFDA attaches great importance to the EU's new API Directive. On February, SFDA participated to the API Directive Information Briefing meeting held in Brussels and had meetings with DG SANCO responsible officials. SFDA talked with DG SANCO officials there and expressed concerns, and DG SANCO officials agreed to consider SFDA's concerns. When Commissioner Dalli and Director-General Paola Testori Coggi visited SFDA in March, both side also exchanged views on this issue.

Nevertheless, EU didn't adopt any comments made by SFDA when published the *Public Consultation on the Draft Template for the Written Confirmation for Active Substances Imported into the EU for Medicinal Products for Human Use*, and insists to require:

1. The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU;

2. The manufacturing plant is subject to regular, strict controls and to the effective enforcement of good manufacturing practice, so as to ensure a protection of public health at least equivalent to that in the EU;

3. In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

At the same time, an additional requirement of "The authenticity of this written confirmation may be verified with the issuing regulatory authority" has been added. Moreover, this Written Confirmation doesn't have "valid duration" as mentioned during the EU-China bilateral meeting, we don't know if it's valid for one time, or valid for a long period.

In view of the problems mentioned above, if the EU insists that the draft templates remains unchanged, it would be very difficult for SFDA to issue that Written Confirmation.

The text of the written confirmation that SFDA could issue is: the API product which is produced by manufacture is compliant with the standard of Chinese pharmaceutical GMP; According to Chinese legislations, China's pharmaceutical supervision authorities conducts regular and irregular controls; In the event of findings relating to non-compliance with Chinese pharmaceutical GMP, according to relevant agreement between China and the EU, SFDA will inform the EU side timely; The written confirmation is valid for 5 years, if there's any change before the expiration date, SFDA will also inform the EU side timely.