DONGCHENG BIOCHEMICALS
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30 May 2012

Health and Consumers Directorate

Re.: SANCO/D6/(2012)ddg1.d6.517666

Public consultation: Directive 2011/62/EC including the draft template for the written confirmation for active substances imported into the EU for medicinal products for human use.

Dear Sir/Madam

Yantai Dongcheng Biochemicals Co.,Ltd., an API manufacturer in China, appreciated to have the opportunity to provide our comments on this Directive including the draft template, and offers the following comments:

As China is out of the approved list by commission and also not a member of any organization who can be waived, each Chinese API manufacturer will be required to provide such written confirmation for each consignment. We do not think it is reasonable to require each Chinese API manufacturer to issue such confirmation from the authorities, actually, it should be considered according to different conditions:

(1) In China, it will be a long way to be an approved API manufacturer. In fact, a manufacturing will be viewed as illegal if a manufacturer does not hold a manufacturing license certificate, authentication code and GMP certificate. So this kind of manufacturing authorization management to API is different from the current management mode applied by EU.

To get such approval, we will have to take about 2-3 years or even more time. A company only can get a GMP certificate when passing an on-site GMP inspection by the authorities and a re-inspection will be necessary each five years. At the same time, every approved company will have to face some unexpected inspections by the local authorities.

The new edition of Chinese GMP, 2010 GMP, has been entered into force. It means the Chinese GMP has been more and more closed to the EU GMP. To our

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understanding, the new requirements regarding the API in this GMP have been totally up to or even stricter than the requirements in the EU GMP.

(2) In addition, some of Chinese API manufacturer have passed the EU GMP inspections by different member's authorities. To us, we have passed several GMP inspections by BGV, Germany, and have got the EU GMP certificate. This GMP inspection will take place each three years to confirm our company is staying in a good GMP status. So it should completely prove our GMP system can meet the requirements of EU GMP. In this case, we should be waived directly instead of under some special conditions.

To the companies with the double certificates from EU member's authorities and Chinese authorities, this directive should not be applicable to them. We think it will be better, if the commission could base on the qualification of the manufacturer to establish a database or establishment list regarding the approved API manufacturer of the third country so that the customs could make a judgment before an inspection.

Regarding the written confirmation, it is also unpractical if asking each consignment accompanied by a written confirmation from the authorities, and for the declaration in the draft confirmation, we are afraid our authorities cannot issue such statement based on the Drug Administration Law of the People's Republic of China.

Dongcheng appreciated the opportunity to provide our comments and hopes these comments are useful in the finalization of this Directive.

Sincerely yours

Yi Qiong

Yi Qiong, Ms

QP

Yantai Dongcheng Biochemicals Co., Ltd.