

23 April 2012

To DG SANCO/D/6

Dear Mr. Fuehring,

Please find attached several comments from CEFIC/ APIC on:

**Delegated Act on the Principles and Guidelines of Good Manufacturing Practice
for Active Substances in Medicinal Products for Human Use**

CEFIC is the organization representing national federations, companies and more than 100 affiliated associations and sector groups, located in Europe. All together CEFIC represents directly or indirectly more than 40,000 large, medium and small chemical companies in Europe, which employ about 2 million people and account for more than 30% of the world's chemical production.

APIC is one of CEFIC sector groups, comprising producers of active pharmaceutical ingredients (APIs) and intermediates in Europe. We highly appreciate this opportunity of submitting our members' comments on the above mentioned document.

We trust that you will take our comments into consideration and look forward to hearing from you soon.

Yours sincerely,

Pieter van der Hoeven
Managing Director APIC

Cefic (European Chemical Industry Council)

E-mail: pvd@cefic.be

Phone: +32.2.676.72.02

(No signature, sent electronically)

Chemistry making a world of difference

European Chemical Industry Council

Avenue E. van Nieuwenhuysse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 02 Fax: +32 2 676 73 59 pvd@cefic.be www.cefic.org