

**FUEHRING Stefan (SANCO)**

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**From:** Nilesh Sheth  
**Sent:** vendredi 18 février 2011 14:52  
**To:** SAN CO PHARMACEUTICALS  
**Subject:** Response to REVISION OF THE 'CLINICAL TRIALS DIRECTIVE' 2001/20/EC - CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION  
**Attachments:** Respose to CTA Directive revision consultation.pdf

Sir/Madam

I attach my response to the above. I am responding in my capacity as a private individual.

I would also like to point out what might be an inconsistency in the consultation document. It concerns Tables 1 and 2 on page 18 of the document. Both tables appear to show the same information i.e. No of clinical trial applications in the EU. From the text on page 18, it seems that Table 1 shows the actual number of trials performed in the EU and Table 2 shows the number of clinical trial applications in the EU which suggests that the Table 1 title '**Number of clinical trials applied for in the EU**' is incorrect.

Kind regards

Nilesh Sheth