LifeConEx
CONNECTING PEOPLE WITH LIFE

April 25, 2013

Sanco-pharmaceuticals-d6@ec.europa.eu
Unit SANCO/D/6, DM24 02/050,
BE-1049 Brussels

Submission of comments on the Revised Commission GUIDELINES ON THE PRINCIPLES OF GOOD DISTRIBUTION PRACTICES FOR ACTIVE SUBSTANCES FOR MEDICINAL PRODUCTS FOR HUMAN USE

Dear Madam, Sir,

LifeConEx, a 100 per cent subsidiary of DHL, offers peace of mind as the only industry-specific, end-to-end cold chain management solutions provider for the life science industry worldwide. With oversight of the entire global landscape, LifeConEx designs and orchestrates the shipment process end-to-end proactively and reactively, assuring the integrity of the product's desired condition. The company believes that proactive management of processes throughout the supply chain should be a universal standard, ensuring products arrive to patients in the right condition, at the right place, and at the right time – it's all about patient safety. LifeConEx is supply chain party neutral (airlines, forwarders, truckers, packaging, and technology).

LifeConEx has reviewed the above referenced document and is providing the following comments for your consideration. LifeConEx welcomes guidance from the Commission and appreciates this opportunity to comment on the subject document. We hope that you will take our comments into consideration.

Should you need additional information or wish to hold further discussions with our company experts, do not hesitate to contact me.

Yours sincerely,

Raul M Bras

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Audit and Regulatory Compliance Manager

Encl.

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Comments from:

LifeConEx

Item Number	LifeConEx Comments
Item 11	Consider including a requirement to do documents periodic reviews as part of the Document Control System.
Item 22	Before destroying immediately damaged package or suspected contaminated stocks, we recommend including a clause to inform the customer.
Item 35	For returns of products this section should include a statement to verify with the customer before returning any stock. (Some customers will never accept returns because the cold chain may be broken while the product was not in their hands).
Item 41	Complaints records minimum retention time is not specified in this section.
General Observation	The guidelines properly reflect ICH Q7 GMP Practice for API - Section 10 - Storage and Distribution; however, LifeConEx recommends improving upon the items listed above.