

## **MOREL Frederique (SANTE)**

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**From:** SANTE PHARMACEUTICALS D6  
**Subject:** FW: Annex 15 Comments

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**From:** Lees, Bev  
**Sent:** Friday, May 23, 2014 12:38 PM  
**To:** SANCO PHARMACEUTICALS D6  
**Subject:** Annex 15 Comments

Dear Sir/Madam,

We would like to propose an addition to section 9.5'Limits for the carry, over of product residues should be based on a toxicological evaluation to determine the product specific permitted daily exposure (PDE) value' We would propose to also add 'if toxicological data is not available a risk based approach should be taken based on available data to set the acceptance criteria for cleaning process validation'

Kind Regards

**Bev Lees** |

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