

MOREL Frederique (SANTE)

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

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 |

 www.allergytherapeutics.com

Disclaimer: This communication (including any attachments) is confidential and may contain information that is legally privileged or exempt from disclosure. The communication is intended only for the use of the addressee(s) named. If you are not an intended recipient, or the employee or agent responsible for delivery to an intended recipient, please note that any unauthorised viewing, copying, printing, storage, dissemination or distribution of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by replying to the message and then delete it from your computer. Security Warning: Please note that this email has been created in the knowledge that Internet email is not a 100% secure communications medium. We advise that you understand and observe this lack of security when emailing us. Viruses: Although we have taken steps to ensure that this email and attachments are free from any virus, we advise that in keeping with good computing practice the recipient should ensure they are actually virus free. Company Registration Details: Allergy Therapeutics plc: Registered in England and Wales under company number 5141592 Registered Office: Dominion Way, Worthing, West Sussex BN14 8SA Allergy Therapeutics (UK) Ltd.: Registered in England and Wales under company number 3489885 Registered Office: Dominion Way, Worthing, West Sussex BN14 8SA