Dear Louise Voller,

Thank you very much for your e-mail and we acknowledge the receipt.

Kindly note that our product is not registered or distributed in US and we have not received any notice from USFDA.

Please be noted that the attached report confirms that this study was carried out in the year 2013 and was submitted to regulatory authorities as part of our regulatory submissions in EU and assessed by the regulators prior to granting marketing authorisation. No concerns were raised till date on this report by any of the regulatory authority. We have not received any regulatory alert in this regard till date.

We can confirm that each batch of the product is tested and confirmed for the compliance to the registered specifications before release for sale and distribution. The stability studies of the product is also being reviewed periodically.

We assure that we have systems in place to monitor the product performance during its lifecycle including addressing any regulatory queries within our quality system and respond to authorities appropriately. Hence we can assure that our products are safe and effective.

As part of lifecycle management that we indicated earlier, we will be performing the risk assessment to identify any risk to patient safety and contact regulators as deemed necessary.

Once again, we thank you for bringing this to our knowledge and we appreciate your support in this regard.

Thanks & regards,

Purnachandrashekar Movva
Associate Director Corporate Quality
Bristol Laboratories Ltd