----- Original Message -----
From: XX
To: Janne Larsson
Sent: Thursday, November 23, 2006 6:39 PM
Subject: FOI 06-252 further reply

Dear Mr Larrson

Thank you for your email of 19 September. I am sorry for the long delay in replying.

I am sorry if our previous replies have caused confusion. I would like to clarify the following:

The safety of Strattera, including review of all serious psychiatric reactions, is considered on an ongoing basis in the periodic safety update reports. A separate review of psychiatric reactions is not required in order for MHRA to have access to these data - they are provided in the regular PSURs. Any changes required to the product information will be made on the basis of those reports.

The request to Lilly for a cumulative review was made on the understanding that they had conducted such a review of psychiatric reactions and submitted it to the FDA. We generally want to have sight of reviews conducted by companies for other regulators to see if we can reach a harmonised approach on any resulting regulatory action. However, it became clear that Lilly had not completed its own review, but had supplied raw data on request of the FDA. **Our own assessment of subsequent periodic safety updates satisfied us that the issue of psychiatric reactions could be appropriately monitored through these updates and there was not a requirement for a separate and cumulative review of psychiatric reactions with Strattera. [Emphasis added.]**

Yours sincerely
XX
XX
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