## R12/1074163



Re: Actos PI and Dear HP Letter [SEC=UNCLASSIFIED]

Bronwen Harvey to: Cc: Nick Simpson

29/06/2011 10:02 PM

Hi

I am very sorry that it has taken me so long to get back to you. I will phone you in the morning to finalise any outstanding issues.

Bronwen

Dr Bronwen Harvey Head, Signal Investigation Unit Office of Product Review Therapeutic Goods Administration Phone: 02 6232 8071

Mobile: 0423 026 409 Email: bronwen.harvey

29/06/2011 11:42:02 AM

29/06/2011 11:41 AM

To Bronwen. Harvey

CC

Subject Re: Actos Pl and Dear HP Letter [SEC=UNCLASSIFIED]

Hi Bronwen

I have just spoken to Nasis to let him know I have submitted an SRN for Actos last Thursday and to explain we had already discussed and agreed the changes with you. While the SRN has not yet reached Nasis he is happy for me to go ahead and implement the new PI on the basis that OPR have agreed to the proposed changes.

This afternoon I will take steps to implement the PI we agreed upon last Thursday, following which we will arrange printing of the Dear HP letter with mailing to HPs to occur as soon as possible thereafter (most likely early next week).

Kind Regards

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