



Re: Actos [SEC=UNCLASSIFIED]

Nick Simpson to: [REDACTED]

20/06/2011 03:08 PM

Dear [REDACTED]

thank you for sending that data so promptly

kind regards

Nick

.....
Nick Simpson MBBS MPH PhD

Medical Officer | Signal Investigation | Office of Product Review | Monitoring and Compliance
Group
Therapeutic Goods Administration | Commonwealth Department of Health and Ageing

phone 02 6232 8092 | fax 02 6232 8392 | nick.simpson [REDACTED] | <http://www.tga.gov.au>

[REDACTED] Dear Nick I have obtained a copy of the CSR f...

20/06/2011 02:21:54 PM

From: [REDACTED]
To: Nick.Simpson [REDACTED]
Cc: Bronwen.Harvey [REDACTED]
Date: 20/06/2011 02:21 PM
Subject: Re: Actos [SEC=UNCLASSIFIED]

Dear Nick

I have obtained a copy of the CSR for the study requested below have provided it on a CD-ROM along with other data of relevance to your. The disc is being sent express post to your attention and should be with you tomorrow. Please let me know if you require any clarification of the information once you receive it.

Kind Regards

[REDACTED]
(Embedded image moved to file: pic24459.jpg)

Nick.Simpson [REDACTED]

[REDACTED]
17/06/2011 11:24
AM

[REDACTED] To
[REDACTED] cc
Bronwen.Harvey [REDACTED]
Subject
Re: Actos [SEC=UNCLASSIFIED]

Dear [REDACTED]

I forgot to ask in the teleconference: have you submitted to TGA the follow-up to PROactive, mentioned in Takeda's response to the KPNC cohort study?

Takeda has recently completed and submitted (under separate cover) the results from the 4-year interim analysis of study AD-4833/EC-445, which is an ongoing, European, multicentre, observational study of subjects who were previously treated in PROactive (AD-4833/EC-444) with pioglitazone or placebo in addition to their existing antidiabetes and cardiovascular medication.

Since this apparently has a bearing on the issue of bladder cancer, would you be able to submit that data too (or if it has been submitted, would you mind providing a reference submission number)?

kind regards

Nick

.....
Nick Simpson MBBS MPH PhD

Medical Officer | Signal Investigation | Office of Product Review |
Monitoring and Compliance Group
Therapeutic Goods Administration | Commonwealth Department of Health and Ageing

phone 02 6232 8092 | fax 02 6232 8392 | nick.simpson [REDACTED] |
<http://www.tga.gov.au>

From: [REDACTED]
To: [REDACTED]
Cc: Bronwen.Harvey [REDACTED] Jane.Cook [REDACTED]
Neil.Mitchell [REDACTED] Nick.Simpson [REDACTED]
Date: 17/06/2011 10:50 AM
Subject: Re: Actos [SEC=UNCLASSIFIED]

Dear Nick

Please find attached the translation of the Afssaps analysis. I will send separately the meta-analysis discussed in our meeting this morning.

(See attached file: 917486_pioglitazone_final CNAMTs report translation with tables.doc)

Kind Regards

[REDACTED]
(Embedded image moved to file: pic18990.jpg)

[REDACTED]
15/06/2011 02:13

To