

Recalls
Sent by: Trevor Byrne

08/12/2010 12:47 PM

To Judy Zilber [REDACTED]
cc Pamela Carter [REDACTED], Virginia Deigan [REDACTED]
O'Connor [REDACTED], Susan Coates [REDACTED], Jai [REDACTED]
Kelly [REDACTED], Penny Lovell [REDACTED], Matthew [REDACTED]
bcc

Subject Fw: RC-2010-RN-01196-3 Distribution of [REDACTED] letter under sectic

UNCLASSIFIED

Dear Judy

the amended text has been sent by email to each of the customers listed (copies of emails on file)

As noted in the 41KA letter, notices can now be prepared for publication in the Commonwealth Gazette and on the TGA's Website after 14 December 2010. Please provide a copy of these for our file once they have been published.

Yours Sincerely

Trevor Byrne
Deputy Recall Coordinator
Office of Product Review
Monitoring & Compliance Group
Therapeutic Goods Administration
Tel: 02 6232 8636
Fax: 02 6203 1451
email: recalls@[REDACTED]

----- Forwarded by Trevor Byrne [REDACTED] on 08/12/2010 12:24 PM -----



08/12/2010 11:14 AM

To <Trevor.Byrne@[REDACTED]>
cc

Subject RE: RC-2010-RN-01196-3 Letter - Decision to Impose Requirements [SEC=UNCLASSIFIED]

Dear Mr Byrne,

The letter containing your amended text has been sent to each customer to-day December 7th 2010. I have copied each email to you so that you will have a record.



Recalls
Sent by:

To peter@[REDACTED]



08/12/2010 11:14 AM

To <Trevor.Byrne@[REDACTED]>

cc

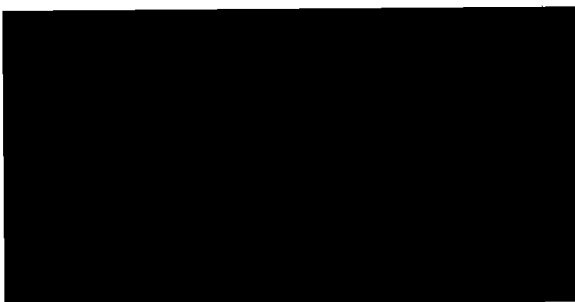
bcc

Subject RE: RC-2010-RN-01196-3 Letter - Decision to Impose Requirements [SEC=UNCLASSIFIED]

UNCLASSIFIED

Dear Mr Byrne,

The letter containing your amended text has been sent to each customer to-day December 7th 2010. I have copied each email to you so that you will have a record.



From: Trevor.Byrne@[REDACTED] [mailto:Trevor.Byrne@[REDACTED]] **On Behalf Of** Recalls@[REDACTED]

Sent: Monday, December 06, 2010 5:46 PM

To: [REDACTED]

Subject: RC-2010-RN-01196-3 Letter - Decision to Impose Requirements [SEC=UNCLASSIFIED]

Dear [REDACTED]

thank you for your proposed letter in response to a notice from Larry Kelly dated 26 November 2010 - 'Decision to impose requirements under section 41KA of the therapeutic Goods Act 1989'.

The TGA has proposed that the text of the your letter be amended to clarify the message to your customers. A copy of the amended text is attached.

If the amended text is also acceptable to [REDACTED] then please send the letter to customers by 21 December 2010. Please provide evidence that the notification has been sent to the customers within two working days after the notification was sent (i.e no later than 24 December 2010)

Please note that the notice from Larry Kelly will be published in the Commonwealth Gazette and on the TGA's Website after 14 December 2010.

Yours Sincerely