

Judy Zilber [REDACTED]  
16/09/2010 08:55 AM

To [REDACTED]  
cc  
bcc

Subject RE: Reminder Letter s41JA 15 Sept 2010 [REDACTED]

UNCLASSIFIED

[REDACTED]  
Thank you for this information.

The information TGA requested was originally due at the TGA by the 7th September 2010. Under the Therapeutic Goods Act you are then given a further 10 working days from that original date in which to provide the information. The Reminder notification has actually allowed you a further 18 days in which to provide the information.. Had you requested an extension at the time of receiving the first notification this would have been about the date to which you would have been given an extension. This extra time constitutes a reasonable extension.

Please provide the information requested by 1 Oct as stated in the Reminder letter or respond with a detailed explanation as to why you, as the sponsor responsible for this device on the ARTG, will not be able to provide all/some of the information requested by that date.

If you have concerns with the TGA's request for information you may lodge an appeal following the guidelines stated in the original letter of Request and attached here again for your information.

Thank you.

Judy Zilber  
TGA

02 62328299



Section 41JA Appeal Provisions.doc



15/09/2010 10:05 PM

To <Judy.Zilber [REDACTED]>  
cc

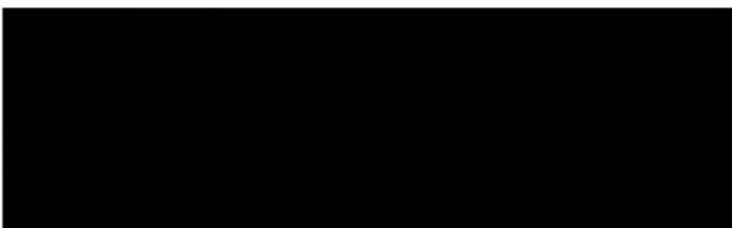
Subject RE: Reminder Letter s41JA 15 Sept 2010  
[SEC=UNCLASSIFIED]

Dear Ms Zilber,

I was informed on September 1<sup>st</sup> that our Australian agent [REDACTED] had contacted your office to request an extension as he was leaving on vacation that day and would handle the request as soon as he returned.

I have forwarded the reminder letter to [REDACTED] and I will call his office again today.

Our Australian agent is:



Sincerely

**From:** Judy.Zilber [mailto:Judy.Zilber]  
**Sent:** Tuesday, September 14, 2010 8:37 PM  
**To:**  
**Subject:** Reminder Letter s41JA 15 Sept 2010 [SEC=UNCLASSIFIED]

your immediate attention to the attached reminder letter is requested.

Thank you  
Judy Zilber  
TGA

02 62328299

-----< TRIM Record Information >-----

Record Number : R10/273710  
Title : Reminder Letter s41JA 15 Sept 2010

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"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information and has been sent in accordance with the TGA security policy.

If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

\*\*\*\*\*  
No virus found in this incoming message.  
Checked by AVG - www.avg.com  
Version: 9.0.851 / Virus Database: 271.1.1/3117 - Release Date: 09/14/10 02:35:00

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