

Judy Zilber [REDACTED]
17/05/2010 02:32 PM

To [REDACTED]
cc
bcc

Subject RE: TRIM: Post Market Review ID 20100028

UNCLASSIFIED

[REDACTED]
Thank you for your update.

As [REDACTED] have had 3 months since the date of the initial letter Request for Information and the responses are now well overdue, I will be considering Proposing to Cancel this product from the ARTG unless the information is with me by this Friday May 21st as well as evidence that [REDACTED] have undertaken steps to cancel the product themselves from the ARTG, as discussed with you on 24 April 2010.

Your assistance in this matter is requested.

Judy Zilber
MVMS
TGA

02 62328299

[REDACTED]



[REDACTED]

14/05/2010 08:31 AM

[REDACTED]

To <Judy.Zilber [REDACTED]>
cc

Subject RE: TRIM: Post Market Review ID 20100028
[SEC=UNCLASSIFIED]

Judy,

Apologies for my delay in replying, I have been in Sydney at a tradeshow and have not been in my normal routine.

I have prepared info to be sent to you and I have been waiting for review of this by the [REDACTED] Director but haven't heard back.

I will package up the info and send to you and also follow up on the ARTG cancellation as I don't know that this has been completed by [REDACTED]

regards

[REDACTED]

[REDACTED]

From: Judy.Zilber [REDACTED] [mailto:Judy.Zilber [REDACTED]]
Sent: Tuesday, 11 May 2010 3:04 PM

To: [REDACTED]

Subject: RE: TRIM: Post Market Review ID 20100028 [SEC=UNCLASSIFIED]

good afternoon [REDACTED]

Can you please provide an update on where you are at with this information? It was expected to be received by today.

Thank you
Judy Zilber
TGA

02 62328299

[REDACTED]

To: Judy.Zilber [REDACTED]

cc

29/04/2010 10:46 AM

Subject: RE: TRIM: Post Market Review ID 20100028 [SEC=UNCLASSIFIED]

[REDACTED]

Judy,

Understood, I am arranging the collation of the information and also the cancellation documentation.

Can you advise are we able to provide the information via electronic means such as a CD?

regards

[REDACTED]

[REDACTED]

From: Judy.Zilber [REDACTED] [mailto:Judy.Zilber [REDACTED]]

Sent: Tuesday, 27 April 2010 4:13 PM

To: [REDACTED]

Subject: Re: TRIM: Post Market Review ID 20100028 [SEC=UNCLASSIFIED]

Good afternoon [REDACTED]

Further to our phone conversation last week there is still some information [REDACTED]
[REDACTED] are requested to provide to the TGA even though they are considering removing the product ARTG number 152697 from the ARTG.

It is noted that the sponsor states they no longer has a working relationship with the overseas manufacturer however it is expected that the sponsor should still be able to provide previous

materials related to this device when the entry was included on the ARTG.

Please arrange to send me the following within **10 working days** from the date of this email, either via email or addressed to my attention Office Devices Blood and Tissues, TGA, PO Box 100, Woden, ACT 2606;

1. all clinical evidence that supports the device and its intended purpose (literature on studies etc)
2. labelling for the device
3. instructions for use for the device
4. advertising of the device including any website advertising.

This information is requested to assist the TGA in the review of this the type of product and its intended use.

Your co-operation with this request is appreciated.

Judy Zilber
Market Vigilance Monitoring Section
TGA

02 62328299

21/04/2010 04:34 PM

To: <judy.zilber@tga.gov.au>

cc:

Subject: TRIM: Post Market Review ID 20100028

Please respond to

Ms. Zilber,

Please refer to attached delegation letter from [REDACTED]
[REDACTED] regarding ARTG Number 152697. I will be in contact tomorrow to discuss matters in relation to the post market review on [REDACTED] behalf.

If you could confirm your contact details by reply.

regards

[REDACTED]

[REDACTED]

[REDACTED]

Information from ESET NOD32 Antivirus, version of virus signature database
5045 (20100420)

The message was checked by ESET NOD32 Antivirus.

<http://www.eset.com>

[attachment "TGAZilber_JADelegateSign_20Apr10.pdf" deleted by Judy Zilber]

"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."

Information from ESET NOD32 Antivirus, version of virus signature database
5070 (20100428)