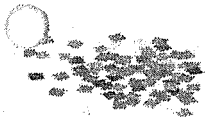


Judy Zilber [redacted]
29/11/2010 08:56 AM

To [redacted]
cc Trevor Byrne [redacted]
bcc
Subject RE: Letter - Decision to Impose Requirements [SEC=UNCLASSIFIED]

UNCLASSIFIED

[redacted]

As this is now a matter for the TGA Recalls Section I have forwarded your email to the Recall Coordinator for his attention.

Please communicate with Mr Trevor Bryne, Recall Coordinator, for anything futher on this matter (as stated in the letter dated 26 Nov 2010).

Thank you.

Judy Zilber

Executive Officer Device Vigilance and Monitoring Office Product Review Monitoring and Compliance Group
Therapeutic Goods Administration
02 62328299

[redacted]

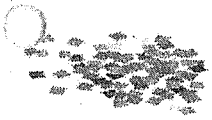
[redacted]
29/11/2010 08:26 AM

To <Judy.Zilber@[redacted]
cc
Subject RE: Letter - Decision to Impose Requirements [SEC=UNCLASSIFIED]

Ms Zilber,
Attached proposed letter for approval.
This letter will be sent to :

[redacted]

From: Judy.Zilber@[redacted] [mailto:Judy.Zilber@[redacted]]
Sent: Thursday, November 25, 2010 11:52 PM
To: [redacted]
Subject: Letter - Decision to Impose Requirements [SEC=UNCLASSIFIED]



Judy Zilber [redacted]
29/11/2010 08:45 AM

To Trevor Byrne [redacted]
cc Pamela Carter [redacted]
bcc
Subject Fw: Letter - Decision to Impose Requirements [SEC=UNCLASSIFIED]

UNCLASSIFIED

Trevor,

As this is now a matter for Recalls could you please respond to [redacted] re the [redacted] camera thermographic?

Thank you.

Judy Zilber

Executive Officer Device Vigilance and Monitoring Office Product Review Monitoring and Compliance Group
Therapeutic Goods Administration
02 62328299

----- Forwarded by Judy Zilber [redacted] on 29/11/2010 08:43 AM -----

[redacted]
29/11/2010 08:26 AM

To <Judy.Zilber@[redacted]
cc
Subject RE: Letter - Decision to Impose Requirements [SEC=UNCLASSIFIED]

Ms Zilber,
Attached proposed letter for approval.
This letter will be sent to :

[redacted]

From: Judy.Zilber@[redacted] [mailto:Judy.Zilber@[redacted]]
Sent: Thursday, November 25, 2010 11:52 PM
To: [redacted]
Subject: Letter - Decision to Impose Requirements [SEC=UNCLASSIFIED]

[redacted]
Attached is a letter with the TGA Decision to Impose Requirements for the device camera thermographic.

Your immediate attention to this letter is required.

A hard copy has also been mailed to [redacted] regulatory affairs agent [redacted]

Judy Zilber

Executive Officer Device Vigilance and Monitoring Office Product Review Monitoring and Compliance Group
Therapeutic Goods Administration
02 62328299

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MMS letter ARTG requirment.pdf

UNCLASSIFIED

[redacted]

November 28th 2010.

Proposed text for distribution to customers for approval

Notification of cancelation of ARTG device number 143474

[redacted] has been instructed by the TGA to notify users of thermography equipment supplied by this company that that equipment as been removed from the register.

(i) the Australian Register of Therapeutic Goods entry for the Device (ARTG number 143474) was cancelled from the Register on 24 September 2010;
(ii) [redacted] requested the Secretary cancel the entry following a request for information and documents from the TGA which included evidence that the Device complied with essential principle 14 (which requires every medical device to have clinical evidence appropriate for the use and classification of the device) set out in the Regulations; and
(iii) that they note the advertising requirements under the Act, the *Therapeutic Goods Advertising Code 2007* (the Code) and the *Trade Practices Act 1974* (TP Act). That is, a person must not publish or broadcast an advertisement about therapeutic goods: if that good is not entered on the Register (refer to section 41DL of the Act), that a therapeutic good cannot be advertised in a manner that is likely to be misleading or likely to lead to consumers inappropriate by treating potentially serious diseases (see section 4(2) of the Code) and that goods generally cannot be advertised in a manner that is likely to mislead or deceive (see section 53 of the TP Act).

[redacted]

[redacted]