44

Recalls
Sent by: Trevor Byrne

07/12/2010 09:45 AM

To peter@[redacted]
cc
bcc
Subject RC-2010-RN-01196-3 Letter - Decision to Impose Requirements [SE

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.

RC-2010-RN-01196-3 - Amended text of product notification.docx

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

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]

[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]

[redacted] has been instructed by the Therapeutic Goods Administration ("TGA") to notify users of thermography equipment supplied by this company (also trading as [redacted] that **Camera, thermagraphic (MED2000, MED2000 PRO, MED2000 IRIS)** with the **ARTG number 143474** (" the Device") has been removed from the Australian Register of Therapeutic Goods ("ARTG"). Specifically we ask that you note the following:

(i) the entry for the Device was cancelled from the ARTG on 24 September 2010;

(ii) [redacted] requested the Secretary cancel the entry following a request for information and documents from the TGA which included a request for evidence that the Device complied with essential principle 14 set out in the *Therapeutic Goods (Medical Devices) Regulations 2002*. Essential principle 14 requires every medical device to have clinical evidence appropriate for the use and classification of the device; and

(iii) that there are advertising requirements for therapeutic goods and medical devices under the *Therapeutic Goods Act 1989* (the Act), the *Therapeutic Goods Advertising Code 2007* (the Code) and the *Trade Practices Act 1974* (TP Act). These requirements include:

- a person must not publish or broadcast an advertisement about therapeutic goods: if that good is not entered on the ARTG (refer to section 42DL(1)(g) 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 inappropriately 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).

Please be aware that penalties may apply for breaches of these requirements.