Penny Lovell [redacted]
30/11/2010 11:43 AM

To Trevor Byrne [redacted]
cc
bcc
Subject [redacted] letter [SEC=UNCLASSIFIED]

UNCLASSIFIED

Sorry Trevor, please ignore previous email, it should read "section 42DL(1)(g) of the Act" not "section 41DL(2)(g) of the Act".

Kind regards

Penny

Penny Lovell
Legal Policy Adviser (Acting)
Office of Product Review
Therapeutic Goods Administration
Ph: (02) 6232 8163

Please note I am out of the office on Fridays.

---- Forwarded by Penny Lovell [redacted] on 30/11/2010 11:42 AM ----

Penny Lovell [redacted]
30/11/2010 11:41 AM

To Trevor Byrne [redacted]
cc
Subject [redacted] letter [SEC=UNCLASSIFIED]

Trevor

One more amendment highlighted in yellow.

Kind regards

Penny

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Legal Policy Adviser (Acting)
Office of Product Review
Therapeutic Goods Administration
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UNCLASSIFIED

Penny Lovell [redacted]
30/11/2010 11:41 AM

To Trevor Byrne [redacted]
cc
bcc
Subject [redacted] letter [SEC=UNCLASSIFIED]

UNCLASSIFIED

Trevor

One more amendment highlighted in yellow.

Kind regards

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UNCLASSIFIED

(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 Therapeutic Goods Administration 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 *Therapeutic Goods (Medical Devices) Regulations 2002*; and

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(iii) that you~~they~~ note 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: ~~at 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 42~~1~~DL(2)(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 ~~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).

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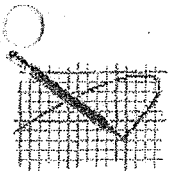

Penny Lovell [redacted]
29/11/2010 02:54 PM

To Trevor Byrne [redacted], Pamela Carter [redacted]
cc Mick O'Connor/ [redacted]
bcc
Subject Letter - [redacted] [SEC=UNCLASSIFIED]

UNCLASSIFIED

Hi Trevor and Pam

I recommend that we amend the draft letter - see tracked changes in **attached** document.

Once you are both happy with the text, I recommend that Terry Lee clear the final letter.

Kind regards

Penny

Penny Lovell
Legal Policy Adviser (Acting)
Office of Product Review
Therapeutic Goods Administration
Ph: (02) 6232 8163

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UNCLASSIFIED

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(iii) that ~~you~~they note 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: ~~at 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(2)(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 ~~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).

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