



Judy Zilber [redacted]
30/11/2010 01:49 PM

To Trevor Byrne [redacted]
cc Pamela Carter [redacted]
bcc

Subject Re: RC-2010-RN-01196-3 Proposed product notification letter for cancelled [redacted] thermographic cameras [SEC=UNCLASSIFIED]

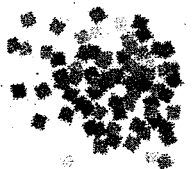
UNCLASSIFIED

Trevor,
I am happy to prepare the paperwork for this gazettal (a process I am very familiar with). The paperwork goes to Larry for final sign off and then the notification goes to Legals. Please let me know if you would like me to complete the gazettal notification for this device (and the 2nd one that is coming).

Judy Zilber

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

Pamela Carter [redacted]



Pamela Carter [redacted]
30/11/2010 01:41 PM

To Trevor Byrne [redacted]
cc Judy Zilber [redacted]

Subject Re: RC-2010-RN-01196-3 Proposed product notification letter for cancelled [redacted] thermographic cameras [SEC=UNCLASSIFIED]

Trevor

Judy Zilber will probably be able to assist with this. She may have already prepared the gazettal notice.

Pam

Pam Carter

Director, Device Vigilance and Monitoring, Office of Product Review, TGA, PO Box 100, Woden ACT 2606

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+61 2 6232 8555

Trevor Byrne [redacted]

Trevor Byrne [redacted]
30/11/2010 01:04 PM

To Terry Lee [redacted]
cc Mick O'Connor [redacted], Pamela Carter [redacted], Jane Cook [redacted], Larry Kelly [redacted], Virginia Deigan [redacted], Penny Lovell [redacted]

Subject RC-2010-RN-01196-3 Proposed product notification letter for cancelled [redacted] thermographic cameras [SEC=UNCLASSIFIED]

Pamela
Carter [REDACTED]
30/11/2010 01:41 PM

To Trevor Byrne [REDACTED]
cc Judy Zilber [REDACTED]
bcc

Subject Re: RC-2010-RN-01196-3 Proposed product
notification letter for cancelled [REDACTED]
thermographic cameras [SEC=UNCLASSIFIED]

UNCLASSIFIED

Trevor

Judy Zilber will probably be able to assist with this. She may have already prepared the gazettel notice.

Pam

Pam Carter

Director, Device Vigilance and Monitoring, Office of Product Review, TGA, PO Box 100, Woden ACT 2606

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+61 2 6232 8555

Trevor Byrne [REDACTED]

Trevor
Byrne [REDACTED]
30/11/2010 01:04 PM

To Terry Lee [REDACTED]
cc Mick O'Connor [REDACTED], Pamela
Carter [REDACTED], Jane
Cook [REDACTED], Larry
Kelly [REDACTED], Virginia
Deigan [REDACTED], Penny
Lovell [REDACTED]

Subject RC-2010-RN-01196-3 Proposed product notification
letter for cancelled [REDACTED] thermographic cameras
[SEC=UNCLASSIFIED]

Dear Terry

re: [REDACTED] s41KA(2)(b) letter signed by Larry Kelly

a proposed letter to be sent to customers of the [REDACTED] thermographic cameras was received yesterday (see attached).

[attachment "MMS letter ARTG requirment.pdf" deleted by Pamela Carter [REDACTED]]

After review by Pam and Penny I propose that the sponsor clarify the message by amending the text of their letter. Please confirm that the attached text would be acceptable.

[attachment "RC-2010-RN-01196-3 Amended product notification text.doc.docx" deleted by Pamela Carter [REDACTED]]

Penny
Lovell [REDACTED]
30/11/2010 01:20 PM

To Pamela Carter [REDACTED]
cc Trevor Byrne [REDACTED]
bcc

Subject RC-2010-RN-01196-3 Proposed product notification
letter for cancelled [REDACTED] thermographic cameras
[SEC=UNCLASSIFIED]

UNCLASSIFIED

Pam

Would you also mind forwarding the s 41KA letter signed by Larry to Terry, and any other background information, to assist her with this?

Cheers

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 01:20 PM -----

Trevor
Byrne [REDACTED]
30/11/2010 01:04 PM

To Terry Lee [REDACTED]
cc Mick O'Connor [REDACTED], Pamela
Carter [REDACTED], Jane
Cook [REDACTED], Larry
Kelly [REDACTED], Virginia
Deigan [REDACTED], Penny
Lovell [REDACTED]
Subject RC-2010-RN-01196-3 Proposed product notification
letter for cancelled [REDACTED] thermographic cameras
[SEC=UNCLASSIFIED]

Dear Terry

re: [REDACTED] s41KA(2)(b) letter signed by Larry Kelly

a proposed letter to be sent to customers of the [REDACTED] thermographic cameras was received yesterday (see attached).



MMS letter ARTG requirement.pdf

After review by Pam and Penny I propose that the sponsor clarify the message by amending the text of their letter. Please confirm that the attached text would be acceptable.

35

Trevor
Byrne
30/11/2010 01:04 PM

To Terry Lee
cc Mick O'Connor, Pamela
Carter, Jane
Cook, Larry
bcc

Subject RC-2010-RN-01196-3 Proposed product notification
letter for cancelled thermographic cameras
[SEC=UNCLASSIFIED]

UNCLASSIFIED

Dear Terry

re: s41KA(2)(b) letter signed by Larry Kelly

a proposed letter to be sent to customers of the thermographic cameras was received
yesterday (see attached).



MMS letter ARTG requirement.pdf

After review by Pam and Penny I propose that the sponsor clarify the message by amending the text of
their letter. Please confirm that the attached text would be acceptable.



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

Also: please advise on the current protocols and templates for publishing notices in the
Commonwealth Gazette

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@

UNCLASSIFIED

Larry Kelly [REDACTED]
30/11/2010 12:00 PM

To Trevor Byrne [REDACTED]
cc Mick O'Connor [REDACTED], Pamela
Carter [REDACTED] Penny
Lovell [REDACTED]
bcc

Subject Re: RC-2010-RN-01196-3 [REDACTED] s41KA(2)(b)
letter. [SEC=UNCLASSIFIED]

UNCLASSIFIED

thanks Trevor. We have stated that we will publish the information in the gazette and on the website.
can you pls give some thought as to what this involves.

Larry

Dr Larry Kelly
Coordinator, Monitoring & Compliance Group
Therapeutic Goods Administration

PO Box 100
Woden
ACT 2606

ph + 61 (0) 2 6232 8700
fax + 61 (0) 2 6232 8687

Trevor Byrne [REDACTED]

Trevor
Byrne [REDACTED]
30/11/2010 11:47 AM

To Larry Kelly [REDACTED]
cc Mick O'Connor [REDACTED]
Subject RC-2010-RN-01196-3 [REDACTED] s41KA(2)(b) letter.
[SEC=UNCLASSIFIED]

Hi Larry

we have received a draft letter from [REDACTED] in line with your s41KA(2)(b) letter. This is being
reviewed by Pam Carter and Penny Lovell.

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]

UNCLASSIFIED

