

CROWE, Brendon

From: Mick O'Connor
Sent: Tuesday, 13 August 2013 2:35 PM
Subject: Re: Need to consider response??:Fw: Contacting the TGA - Alleged breach of advertising - Fluoride [DLM=For-Official-Use-Only]

Dave

I'm not convinced this is a matter for Advertising

David Poulton/TGA/Health
Mick O'Connor/TGA/Health@TTRA
Anthony Gill/TGA/Health@TTRA
8/2013 11:35 AM

Need to consider response??:Fw: Contacting the TGA - Alleged breach of advertising - Fluoride [SEC=UNCLASSIFIED]

Mick

Up until now the fluoride issue has revolved around scheduling (where I have been involved in giving advice) and the interpretation of the excluded goods orders on water purification.

This now raises a new question, whether there has been a breach of the advertising requirements.

I will leave my folder with you and arrange a meeting for us to discuss the Section input.

Dave

Advertising Projects Officer
Recalls and Advertising Section
Office of Product Review

Tel: +61 2 6232 8560 (Mon-Thu 0900 - 1600)

Fax: +61 2 6232 8577

Address: PO Box 100, WODEN ACT 2606

Email: david.poulton@tga.gov.au

----- Forwarded by David Poulton/TGA/Health on 13/08/2013 11:30 AM -----

Anthony Gill/TGA/Health

.Kelly@tga.gov.au, Lisa Studdert/TGA/Health@TTRA, "Philippa Horner" <Philippa.Horner@tga.gov.au>, Anthony Hobbs/TGA/Health@TTRA, "Bill Turner" <Bill.Turner@tga.gov.au>, "Terry Lee" <Terry.Lee@tga.gov.au>, Ruth.Lopert@tga.gov.au

; Mick O'Connor" <mick.o'connor@tga.gov.au>, Paul Maxwell Shepherd/TGA/Health@TTRA, Marlene Keese/TGA/Health@TTRA, David Poulton/TGA/Health@TTRA, TGA Info/TGA/Health@TTRA, Bart Shanahan/TGA/Health@TTRA, Gary Lacey/TGA/Health@TTRA
8/2013 11:24 AM

Fw: Contacting the TGA - Alleged breach of advertising - Fluoride [SEC=UNCLASSIFIED]

Dear all

A new line/s being used in the fluoride issue bringing in advertising. The two emails below are from TAS Health and VIC Health asking for advice.

TGA will need respond.

Tony

Dr Tony Gill | MBBS MPH FAFPHM AFACHSM | Senior Medical Adviser | Office of Scientific Evaluation | Therapeutic Goods Administration | PO Box 100, WODEN ACT 2606 | Ph: 02 6232 8395 | Fax: 02 6232 8239 | Mob: 0432 758 162 | Email: anthony.gill@tga.gov.au

----- Forwarded by Anthony Gill/TGA/Health on 13/08/2013 11:15 AM -----

Info/TGA/Health
ony Gill/TGA/Health@TTRA
esarin/TGA/Health@TTRA
8/2013 10:41 AM

Fw: Contacting the TGA - Alleged breach of advertising - Fluoride [SEC=UNCLASSIFIED]
Sharon Woods

Good morning Tony

Please find attached an email for your follow up and response.

Kind regards

Sharon
Public Contact Team
Therapeutic Goods Administration

Phone: 1800 020 653
Email: info@tga.gov.au

Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
Woden ACT 2606
www.tga.gov.au



----- Forwarded by Sharon Woods/TGA/Health on 13/08/2013 10:40 AM -----

info@tga.gov.au <info@tga.gov.au>
8/2013 09:41 AM

Contacting the TGA - Alleged breach of advertising

Hi there

The following letter was received by our Health Minister last week from a resident of Queensland. It makes an allegation that statements that our Agency makes on our website and in our fact sheet/letters etc about the benefits of fluoridation would be in breach of TGA advertising legislation.

"I write this pursuant to Part II Section 45 Innocent Intentions of the Criminal Code Act 1899.

It has come to my attention that your Department's advertisements (including, but not limited to, fact sheets, brochures and website content) in relation to fluorides used in the fluoridation of drinking water supplies, may include content which may be in breach of the Therapeutic Goods Advertising Code of 2007 and the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011.

The Therapeutic Goods Administration (TGA) have advised myself and others that fluorides used in the fluoridation of drinking water supplies are included in Section 5 Item 10 of the current Excluded Goods Order, ie.

Substances for use in the purification or treatment of drinking water ...If no claims are made for therapeutic use

Please refer to the legislative instrument for the full text:

Therapeutic Goods Act 1989 Therapeutic Goods (Excluded Goods) Order No. 1 of 2011

In the case of fluorides used in the fluoridation of drinking water supplies, your Department is making a therapeutic claim ie effectively prevents tooth decay, helps prevent dental decay (and other words to that effect), which is in breach of the Excluded Goods Order above.

In addition, advertisements including, but not limited to, "has proven a safe and effective measure in the prevention of dental health problems", as well as endorsements by professional organizations (NHMRC, IDF, IADR, WHO), may not comply with sections of the Therapeutic Goods Advertising Code.

Back to toas well as endorsements by professional organizations (eg WHO, NHMRC, ADA and AMA), may not comply with sections of the Therapeutic Goods Advertising Code.

I would therefore respectfully request that you ensure that your therapeutic claims and relevant advertisements comply with the current legislation as noted above.

If I do not hear from you within 28 days, I shall take it that the above information is correct and that your Department will act in accordance with the legislation forthwith, failing which I shall take the matter to the relevant Ombudsman for failure to adhere to current legislation, without any further advise. "

I'm not aware if this person has written to other State or Territory jurisdictions so apologies if you have been approached about this already.

Your advice would be appreciated before we respond to this complainant.

Thanks in advance,

Population Health | Department of Health and Human Services

3/25 Argyle St Hobart GPO Box 125 Hobart Tas 7001

A fair and healthy Tasmania

From:

thga.gov.au,

8/2013 02:53 PM

Assistance please

The following letter has been sent to Government departments in different jurisdictions. I am wondering if you have prepared a response or if there is someone there who could assist with a response. The Correspondent is from [REDACTED]

(See attached file: Copy of (DHD-13-14961) -- Copy of letter from [REDACTED] alleging water fluoridation breaches the TGA code of 2007 - 2013-06-12.DOC)

Thank you for your assistance

regards, [REDACTED]

(Embedded image moved to file: pic24801.jpg)

(Embedded image moved to file: pic16453.jpg)

[REDACTED]
Health Protection Branch | Department of Health
50 Lonsdale Street, Melbourne, Victoria, 3000

[REDACTED]
www.health.vic.gov.au/water

[attachment "Copy of (DHD-13-14961) -- Copy of letter from [REDACTED] -08-
[REDACTED] alleging water fluoridation breaches the TGA code of 2007, 2013
12.DOC" deleted by Mick O'Connor/TGA/Health] [attachment "pic16453.jpg" deleted by
Mick O'Connor/TGA/Health] [attachment "pic24801.jpg" deleted by Mick
O'Connor/TGA/Health]

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