



**RE: Nicoventures: Pre-Submission meeting on a novel Nicotine
Therapeutic Good [DLM=For-Official-Use-Only]**

Bill Turner to: Peter Bird, Lisa Studdert, Anthony Gill

15/11/2013 06:59 PM

Thanks Peter. I would like to be involved and I think Tony Gill perhaps should also be there so we can get his input on the scheduling issues.

Regards,

Bill Turner
Branch Head
Office of Scientific Evaluation

Phone: 02 6232 8187

Email: bill.turner@[REDACTED]

Therapeutic Goods Administration
Department of Health
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Woden ACT 2606
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Sent with Good (www.good.com)

----- Original Message -----

From : Peter Bird/TGA/Health
To : Lisa Studdert [REDACTED] Bill Turner [REDACTED]
Cc :
Sent on : 15/11 04:44:14 PM ZE10
Subject : Fw: Nicoventures: Pre-Submission meeting on a novel Nicotine Therapeutic Good
[DLM=For-Official-Use-Only]

Hi Lisa and Bill,
Given that a TGA group is looking into ecigs, please can you advise me about the request below with regards to accepting the meeting and who should attend - other than those that would directly assess the application. I think the reference below to 'novel nicotine technologies' is really an ecig of some sort. [REDACTED] on their nicotine products. [REDACTED]

Thanks,
Pete

Dr Peter Bird
Head of Office
Office of Medicines Authorisation
Therapeutic Goods Administration
Tel: (02) 62328100

----- Forwarded by Peter Bird/TGA/Health on 15/11/2013 04:34 PM -----

From: Nicoventures [REDACTED]
To: Peter Bird <peter.bird@[REDACTED]>

Dear Peter,

As discussed last week, Nicoventures Limited is in the process of initiating regulatory activity in Australia to bring to market novel nicotine technologies.

As such we would like to arrange an initial face-to-face meeting with TGA. Nicoventures representatives would be myself and our [REDACTED]

The purpose of the meeting would be to discuss our experiences in the US and UK plus our proposed first product and regulatory submission options in the Australia. We anticipate formal regulatory approval from MHRA for our first technology in the very near future, we hope to progress Australian submissions soon after this.

[REDACTED] will be in Australia from the UK the week of 16th December on other business, so it would be great if we could arrange an initial meeting to coincide with this. [REDACTED] presence would be of particular benefit as he has lead similar dialogues recently with both the MHRA in the UK, and FDA in USA.

Given the dynamic, and evolving, nature of this area we have found these face-to-face meetings to be extremely productive for us to better understand agency needs, and also to fully explain our medicines based approach to those agencies.

Appreciate your time is at a premium, however, I hope you can find time during the week of 16th December to see us.

Look forward to your response on this.

Regards

[REDACTED]
[REDACTED]
[REDACTED]

Nicoventures Limited

[REDACTED]

[REDACTED]

www.nicoventures.co.uk

Background on Nicoventures

Nicoventures is a consumer healthcare company established to focus exclusively on bringing nicotine products to smokers that can be licensed to medicines standards. It is a stand-alone company within the British American Tobacco Group, managed separately from the tobacco businesses. The Nicoventures team has extensive pharmaceutical experience of nicotine replacement therapy (NRT) coupled with an understanding of smoking behaviour, which we believe will be of immeasurable value in providing consumers with products that they want to use and that are substantially safer alternatives in comparison with their usual cigarettes. The goal of reducing the harm caused by smoking is a public health benefit to which we openly aspire.

[REDACTED]
[REDACTED]

Nicoventures Limited

[REDACTED]

[REDACTED]

www.nicoventures.co.uk

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