



Re: Fw: Nicoventures: Pre-Submission meeting on a novel Nicotine  
Therapeutic Good [SEC=UNCLASSIFIED]

to: Peter.Bird

25/11/2013 07:25 PM

thanks Peter

that will be great

I will be in touch shortly

many thanks

[REDACTED]

From: Peter.Bird [REDACTED]  
To: [REDACTED]  
Cc: Kylie.Lisson [REDACTED]  
Date: 24/11/2013 22:28  
Subject: Fw: Nicoventures: Pre-Submission meeting on a novel Nicotine Therapeutic Good [SEC=UNCLASSIFIED]

Dear [REDACTED]

I left a message on your mobile phone, but it has occurred to me that you are probably travelling and may not have picked it up. There should not be any problem with meeting that week and you may like to clarify an agenda and suggest a time and date. Kylie Lisson will organise my availability and that of others from the TGA that may need to attend.

Kind regards,

Peter

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

----- Forwarded by Peter Bird/TGA/Health on 25/11/2013 09:24 AM -----

From: Peter Bird/TGA/Health  
To: Peter Bird/[REDACTED]  
Date: 20/11/2013 10:02 AM  
Subject: Fw: Nicoventures: Pre-Submission meeting on a novel Nicotine Therapeutic Good [SEC=UNCLASSIFIED]  
Sent by: Kylie Lisson

From: Nicoventures [REDACTED]  
To: Peter Bird <peter.bird [REDACTED]>  
Date: 11/11/2013 10:52 AM  
Subject: Nicoventures: Pre-Submission meeting on a novel Nicotine Therapeutic Good

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]

**Nicoventures Limited**

[REDACTED]

[REDACTED]

[www.nicoventures.co.uk](http://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](http://www.nicoventures.co.uk)**

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