



**Rescheduled: Nicoventures: Pre-Submission meeting on a novel
Nicotine Therapeutic Good [SEC=UNCLASSIFIED]
Fri 20/12/2013 9:00 AM - 10:30 AM**

Location: Meeting room 8 - TGA Building, 1st Floor B wing - 136 Narrabundah Lane
Symonston ACT

This reschedule notice has been applied to the meeting.
Thank you all for accommodating this meeting.

Required: John Skinner [REDACTED] Kerri Mackay [REDACTED] Mayada
Kayali [REDACTED] Peter Bird [REDACTED]
Optional: Mark McDonald [REDACTED]

Description

Peter,

for date and time December 18th at 10am would be ideal, but if easier for you and others can do 19th or 20th, and be flexible with start time. We can be available for as long as you need during the day, however, if you can spare 90min for the session that would be great.

I will provide you with a formal agenda etc by the end of the week if that's ok.

Overall the intention is to provide you background, and seek feedback, on the products that we will be bringing for review and launch in Australia during 2014. Key areas we would like to cover:-

COMPANY - Nicoventures - who we are and what is our approach to new NRT products

PRODUCTS - Review of the different technologies and data that support our products

PROCESS - Regulatory update on UK submissions and anticipated regulatory route to market in Australia for Nicoventures and other Nicotine containing products

Q&A

Thanks again for making time to see us, this is an area of much focus globally and we are committed to bringing these products to market and so reducing the harm caused by smoking in the population.

Regards

[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.

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.

██████████ 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. ██████████ 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

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Nicoventures Limited

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