

**From:** [REDACTED]  
**To:** [REDACTED]  
**Cc:** [REDACTED] [RMP Coordinator](#)  
**Subject:** RE: Potential RMP evaluation request - BRALTUS PM-2017-03103-1-5 [DLM=For-Official-Use-Only]  
**Date:** Friday, 10 August 2018 9:25:32 AM  
**Attachments:** [image001.png](#)

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Hi [REDACTED]

We'd be happy to review the DHCP letter when it is provided – we can do it informally (in terms of work process), or is a more formal process is preferred then I think it could be assigned to us as a secondary evaluation. Happy either way.

We can also review the PI and/or label if that would be helpful (or will clinical look at this?).

Kind regards,

[REDACTED]

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**From:** [REDACTED]  
**Sent:** Thursday, 9 August 2018 5:48 PM  
**To:** [REDACTED]  
**Subject:** Potential RMP evaluation request - BRALTUS PM-2017-03103-1-5 [DLM=For-Official-Use-Only]

Hi [REDACTED]

I'm currently (only 1 more day left) acting for [REDACTED]

One of the submissions assigned to [REDACTED] is for a tiotropium bromide inhalation by Teva and is being considered as a generic version of Spiriva (dry powder inhaler).

The issue we have is that Spiriva is labelled as containing tiotropium bromide 18 micrograms whereas the generic contains only 13 micrograms per capsule.

- o Note that both products deliver the same quantity of tiotropium per inhalation (10 micrograms)

The company has proposed to provide a Dear Healthcare Provider letter outlining the difference and similarities of the reference and generic products – in addition to statements in the PI and hopefully label.

The DCHP letter proposed for Australia has not yet been provided and I will be asking for it in response to our MS5 report.

The clinical unit would prefer if the RMP team had a look over the DHCP letter etc. Would you be amenable to arranging someone to have a look over the documents once they come in?

Thanks in advance,

[REDACTED]

[REDACTED]

[REDACTED] Pharmaceutical Chemistry Section

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Scientific Evaluation Branch | Medicines Regulation Division  
 Health Products Regulation Group  
 Australian Government Department of Health

[REDACTED]

[REDACTED]

PO Box 100, Canberra ACT 2601, Australia

*The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.*