

From: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]
Subject: FW: PM-2017-03103-1-5 - BRALTUS - Request for information & updated PI [SEC=UNCLASSIFIED]
Date: Tuesday, 2 October 2018 2:12:34 PM
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)
[Milestone 5 FileNote Response.zip](#)

Hi [REDACTED]
Could you please check and let [REDACTED] know if you are satisfied. (Talk to me if you need to).

From: [REDACTED]
Sent: Tuesday, 2 October 2018 12:59 PM
To: [REDACTED]
Subject: FW: PM-2017-03103-1-5 - BRALTUS - Request for information & updated PI [SEC=UNCLASSIFIED]
Are you happy with the labels

From: [REDACTED]
Sent: Friday, 28 September 2018 3:56 PM
To: [REDACTED]
Subject: FW: PM-2017-03103-1-5 - BRALTUS - Request for information & updated PI [SEC=UNCLASSIFIED]

Hi [REDACTED]
See sponsor's response for consideration.
Regards
[REDACTED]

From: [REDACTED]
Sent: Friday, 28 September 2018 11:40 AM
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: PM-2017-03103-1-5 - BRALTUS - Request for information & updated PI [SEC=UNCLASSIFIED]

Dear [REDACTED]
Please find attached a zipped file containing the response to the Delegate's Milestone 5 FileNote for BRALTUS.
The response package also includes the updated PI (consolidated annotations and clean) that reflects the delegate's recommendations. The requested amendments have also been made to the proposed PI in the new format.
The response package will be provided in an eCTD sequence via streamlined submissions next week.
Kind regards

[REDACTED]

[REDACTED]

cid:image003.png@01CA0EA1.81ECBE20



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email



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From: [REDACTED]@health.gov.au]

Sent: Tuesday, 25 September 2018 9:30 AM

To: [REDACTED]

Subject: RE: PM-2017-03103-1-5 - BRALTUS - Request for information & updated PI

[SEC=UNCLASSIFIED]

Dear [REDACTED]

The response and the updated PI should be provided in one package. If all these will not be ready by the timeline suggested by the TGA, you can request for an extension to the time. You can provide your response by email and submit the information as an eCTD sequence at a later date. I note that you also provided the proposed PI in the new format. It will be helpful for you to also include the requested amendment to this version of the PI.

I hope this helps.

Thank you

Regards

[REDACTED]

[REDACTED]

Prescription Medicines Authorisation Branch

[REDACTED]

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: [REDACTED]

Sent: Tuesday, 25 September 2018 7:40 AM

To: [REDACTED]

Subject: RE: PM-2017-03103-1-5 - BRALTUS - Request for information & updated PI

[SEC=UNCLASSIFIED]

Dear [REDACTED]

I acknowledge receipt of the Delegate's File Note.

We will provide an updated PI by COB 28 September.

Can I please clarify how the response should be provided:

- is the response to the additional recommendations required by 28 September?
- can the response be emailed in the first instance with a commitment to provide the response in an eCTD sequence?

Kind regards

[REDACTED]

[REDACTED]



[REDACTED]

From: [REDACTED] [\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)

Sent: Monday, 24 September 2018 4:58 PM

To: [REDACTED]

Subject: PM-2017-03103-1-5 - BRALTUS - Request for information & updated PI
[SEC=UNCLASSIFIED]

Dear [REDACTED]

Find attached evaluation report (Delegate's File Note) on above submission for your consideration. Note that the File Note is based on the version of the PI in the old format. Provide updated PI (**consolidated annotations & clean**) that reflects the delegate's recommendations by **COB Friday 28 September 2018** to enable the finalisation of the submission.

I will appreciate an email acknowledging receipt of this correspondence.

Do not hesitate to contact me if you have any questions regarding this request.

Thank you

Regards

[REDACTED]

Prescription Medicines Authorisation Branch

[REDACTED]

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

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