

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).

[REDACTED]
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

[REDACTED]
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]
cid:image003.png@01CA0EA1.81ECBE20



[REDACTED]
RAPS-Enterprise-Member-Logo



Kind regards



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



Prescription Medicines Authorisation Branch



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.

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."