From: [redacted]
To:
Cc:
Subject: FW: Potential RMP evaluation request - BRALTUS PM-2017-03103-1-5 [DLM=For-Official-Use-Only]
Date: Tuesday, 4 September 2018 1:38:59 PM
Attachments: image001.png
RE PM-2017-03103-1-5 BRALTUS Response to Milestone 5 e0002646 (seq 0004) DLMFor-Official-Use-Only.msg
image002.png

Hi [redacted]
Could you please review the DHCP letter, labels and PI as described in the emails below? I have asked Michael to give us a timeframe.
Kind regards

[redacted]
Risk Management Plan Evaluation
Pharmacovigilance and Special Access Branch

Phone: [redacted]
Email: [redacted]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

[redacted]

From: [redacted]
Sent: Monday, 3 September 2018 11:39 AM
To: [redacted]
Cc:
Subject: RE: Potential RMP evaluation request - BRALTUS PM-2017-03103-1-5 [DLM=For-Official-Use-Only]
Hi [redacted]
The DHCP letter has been provided by the sponsor (e002646 (0004) - Response to request for information - Milestone 5 Request for Information - Quality and Clinical). We would appreciate it you could look at this as well as the PI, labels and any Australian specific requirements. I have asked [redacted] (Streamlined submission) to create an evaluation event for you.
Clinical have looked at the PI and have made some additional suggestions as per the attached email. These have not been sent to the sponsor yet.
In terms of the labels, we (PCS) would prefer that the delivered dose was displayed in a more prominent location in addition to the metered dose. See below for an example:
Braltus
Tiotropium (as bromide) 13 microgram metered dose
Tiotropium (as bromide) 10 microgram delivered dose

If you agree with these changes to the label and PI we will ask the sponsor to update their labels and PI with any additional questions you might have.
Thanks and all the best,

[redacted]
Pharmaceutical Chemistry
Scientific Evaluation Branch

[redacted]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: [redacted]
Sent: Friday, 10 August 2018 9:43 AM
To: [redacted]
Cc: [redacted]
Subject: RE: Potential RMP evaluation request - BRALTUS PM-2017-03103-1-5 [DLM=For-Official-Use-Only]

Hi [redacted]

The clinical unit have made some recommendations regarding labelling and PI aspects already (CER 1 & 2) so it might end up being a bit of a mixture.
The MS5 reports have not yet gone out, although should be shortly. I [redacted] will let you (RMP Coord.) know once the response and DHCP is in.
Thanks,

[redacted]
Principal Evaluator (A/g)|Pharmaceutical Chemistry Section

Scientific Evaluation Branch | Medicines Regulation Division
Health Products Regulation Group
Australian Government Department of Health
[redacted]
Location: Symonston
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.

From: [redacted]
Sent: Friday, 10 August 2018 9:26 AM
To: [redacted]
Cc: [redacted] RMP Coordinator
Subject: RE: Potential RMP evaluation request - BRALTUS PM-2017-03103-1-5 [DLM=For-Official-Use-Only]

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]

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]s for a tiotropium bromide inhalation by Teva and is being considered as a generic version of Spirva (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.

- 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]

Principal Evaluator (A/g)|Pharmaceutical Chemistry Section

Scientific Evaluation Branch | Medicines Regulation Division
Health Products Regulation Group
Australian Government Department of Health
[redacted]
Location: Symonston
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.

From: [redacted]
To:
Cc: Streamlined Submission [redacted]
Subject: RE: PM-2017-03103-1-5 BRALTUS Response to Milestone 5 e0002646 (seq 0004) [DLM=For-Official-Use-Only]
Date: Friday, 31 August 2018 11:47:15 AM
Attachments: image005.gif
image006.png
image007.png
image008.png
image009.png

Hi [redacted]
We have reviewed the sponsor's milestone 5 response.
With regards to the recommended PI changes after round 2 evaluation, the sponsor has not included the following proposed statements:

1. Name of the medicine: Braltus is a generic product of Spiriva (See Braltus pharmacokinetic profile under PHARMACOLOGY).
2. Describe about the comparability (therapeutic equivalence) of Braltus to Spiriva under "Braltus pharmacokinetic profile" heading as: The comparability of Braltus and Spiriva was made on the basis of findings related to their physiochemical, flow geometry, particle size and distribution and systemic bioequivalence study.

These statements were recommend to clarify that in spite of the difference in API between Spiriva and Braltus, systemic bioequivalence was demonstrated and hence Braltus is a generic product of Spiriva. Also, to describe the regulatory basis of our conclusion. Hence, from a clinical perspective, we think it's important to include these statements in PI to provide these information to the prescribers and pharmacists that would help them to make an informed decision. These recommendations are for the consideration of PCES Delegate.
Best regards
[redacted]

From: [redacted] **n Behalf Of** Streamlined Submission
Sent: Thursday, 30 August 2018 10:56 AM
To: [redacted]
Cc: [redacted]
Subject: FW: PM-2017-03103-1-5 BRALTUS Response to Milestone 5 e0002646 (seq 0004) [DLM=For-Official-Use-Only]
Dear all,

Please see docuBridge link below containing the Milestone 5 Responses for submission PM-2017-03103-1-5 BRALTUS (tiotropium).
docuBridge link: e002646 - (0004)
Kind regards,
[redacted]
Technical Case Manager
Application & Advisory Management Section
Prescription Medicines Authorisation Branch

[redacted]

Therapeutic Goods Administration
Department of Health

PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

All enquiries related to the Prescription Medicine Registration Process are to be directed to streamlinedsubmission@health.gov.au
If your enquiry relates to a specific application, please include the submission number in the subject line so that the email is directed to the appropriate case manager.

From: [redacted] **n Behalf Of** eSubmissions
Sent: Tuesday, 28 August 2018 10:27 AM
To: Streamlined Submission
Subject: FW: PM-2017-03103-1-5 BRALTUS Response to Milestone 5 e0002646 (seq 0004) [SEC=UNCLASSIFIED]

Hi All,

The following has been sent directly to eSubmissions, Please save to TRIM.

docuBridge link: e002646 - (0004)

Kind regards,

[redacted]
Records Officer
Enterprise Solutions Branch | Information Technology Division
Australian Government Department of Health
[redacted]
Location: Symonston
PO Box 100, Woden ACT 2606, Australia

From: [redacted]
Sent: Tuesday, 28 August 2018 10:03 AM
To: Streamlined Submission
Cc: eSubmissions; [redacted]
Subject: PM-2017-03103-1-5 BRALTUS Response to Milestone 5 e0002646 (seq 0004) [SEC=No Protective Marking]

Good Morning [redacted]

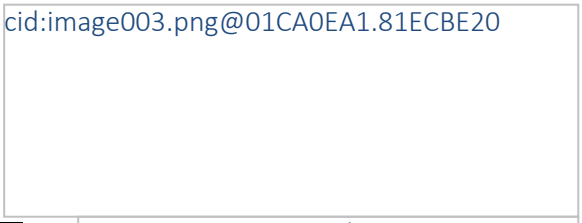
Please find attached eCTD Sequence 0004 containing the Response to Milestone 5 Request for Information –Quality and Clinical.

Trade name(s): BRALTUS
Active ingredient: Tiotropium (as tiotropium bromide)
Strength(s): 13 microgram
Dosage form: Dry Powder for Inhalation, hard capsules
eSubmission ID: e002646

Please confirm receipt of this sequence.

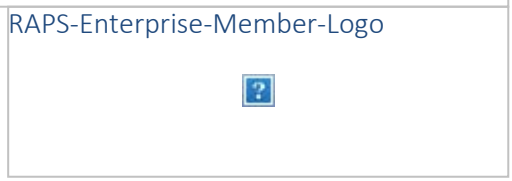
Kind regards

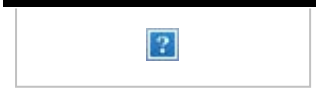
[redacted]



Eight Mile Plains QLD 4113
Australia

[redacted]





Click on the icon to connect with us today!