From: [redacted]
To: [redacted]
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] **On 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] **On 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]
Enterprise Solutions Branch | Information Technology Division
Australian Government Department of Health
[redacted]
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]