From: pbslisting
To: PBAC
Cc: [redacted]
Subject: FW: Advice required on submission pathway [SEC=UNCLASSIFIED]
Date: Thursday, 2 August 2018 3:14:55 PM
Attachments: image001.png

[redacted]

PBS Information Management | Pricing and Policy Branch | Department of Health
Phone: [redacted]
Mail Drop Point 903 | GPO Box 9848 | Canberra ACT 2601 [redacted] 23 Furzer Street | Phillip ACT 2606
Listing Requirements – New Brand | Summary of Deadlines | Guarantee of Supply | PBS forms

From: [redacted]
Sent: Thursday, 2 August 2018 3:07 PM
To: [redacted]
Cc: [redacted] pbslisting
Subject: RE: Advice required on submission pathway [SEC=UNCLASSIFIED]

[redacted]

PBS Information Management | Pricing and Policy Branch | Department of Health
Phone: [redacted]
Mail Drop Point 903 | GPO Box 9848 | Canberra ACT 2601 [redacted] 23 Furzer Street | Phillip ACT 2606
Listing Requirements – New Brand | Summary of Deadlines | Guarantee of Supply | PBS forms

From: [redacted]
Sent: Tuesday, 31 July 2018 10:09 AM
To: [redacted]
Cc: [redacted]
Subject: FW: Advice required on submission pathway [SEC=UNCLASSIFIED]

[redacted]

PBS Information Management
Pricing and Policy Branch
Phone: [redacted]
Department of Health
GPO Box 9848
Canberra, ACT 2601, Australia
Website: www.health.gov.au

From: PBAC
Sent: Monday, 30 July 2018 11:35 AM
To: [redacted]
Subject: FW: Advice required on submission pathway [SEC=UNCLASSIFIED]

[redacted]

From: [redacted]@tevapharm.com]
Sent: Wednesday, 25 July 2018 6:27 PM
To: PBAC
Subject: Advice required on submission pathway [SEC=No Protective Marking]

Dear Secretariat

Teva Pharma Australia currently has a TGA registration application in review for a bioequivalent brand of Spiriva (tiotropium), under the tradename Braltus.

Each pack of the bioequivalent product will be supplied with a Braltus specific inhalation device (Zonda), akin to the Handihaler device used for inhalation of Spiriva. The two products have been proven to be bioequivalent in terms of delivered dose (10 mcg) and will both bear the same dosages instructions in terms of one capsule per day.

Whilst the delivered dose for both brands is 10 mcg thus resulting in bioequivalence, the labelled unit dose strength of the Spiriva and Braltus capsules differ (Spiriva is tiotropium 18 microgram, Braltus is tiotropium 13 microgram). Labelling convention in Australia is in accordance with the relevant Therapeutic Goods Order requiring that pre-metered dose strength be declared on the label. However, the link from pre-metered to delivered and the established bioequivalence will be described in the PI and CMI documents. The inhaler instructions in this case are very similar across the two products.

Having recently been through a PBS listing process for another dry powder inhaler that presented many challenges I would be grateful for advice from the department as to the process that will be required to initiate launch proceedings in this case. Initiation of any activity is subject to legal clearance with the timing unconfirmed at this point. However, you earliest advice on whether a PBAC recommendation is required for this generic would be much appreciated.

If the matter is easier to discuss over the telephone I remain at your disposal on the number below. Alternatively, preliminary email advice on whether a minor PBAC submission or secretariat listing is required would be much appreciated.

Finally, in the event that a minor PBAC submission is required but where we find ourselves ~2 weeks from receipt of a TGA approval at the submission cut off, could we commit to follow up with the TGA approval letter? No activity would be initiated unless we were fully aware that all outstanding TGA matters had been satisfactorily address and that we were just awaiting final processing of the TGA approval letter.

To assist in addressing this query I can advise that [redacted] is aware of our earlier history in relation to DPI generics and may be in a good position to share relevant advice.

Regards and thanks

[redacted]

[redacted] Scientific Affairs ANZ
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