

From: Denloye, Aderonke O <Ade.Denloye@baxalta.com>  
Sent: Tuesday, May 17, 2016 1:03 PM  
To: Maruna, Thomas  
Cc: Reed, Jennifer  
Subject: RE: Late-Cycle-Meeting Status

Dear Lt. Maruna:

Baxalta agrees to cancel the LCM. However we would like to obtain FDA feedback on the following:

? Vial and Carton Label: In SEQ 0018, Baxalta submitted updated carton and vial label artwork,

When can Baxalta expect FDA feedback on this?

? Prescribing Information: Also in SEQ 0018, Baxalta responded to FDA request for information

dated 11 April 2016 to include safety data from the 170903 clinical study in the prescribing

information. When should we expect the label negotiations to begin?

? Release Protocol: We have submitted in SEQ 0022 the draft release protocol, when should we

expect this document to be finalized.

Thanks and looking forward to hearing from you.

Best regards,  
Aderonke Denloye, MPH  
Associate Director, Global Regulatory Affairs  
Baxalta US Inc.  
One Baxter Way  
Westlake Village, CA 91362 USA  
+1 805 372 3053 desk  
+1 805 372 3052 Facsimile  
ade.denloye@baxalta.com

From: Maruna, Thomas [mailto:Thomas.Maruna@fda.hhs.gov]  
Sent: Monday, May 16, 2016 1:30 PM  
To: Denloye, Aderonke O  
Cc: Reed, Jennifer  
Subject: RE: Late-Cycle-Meeting Status

Yes. The only agenda item would be the outstanding PMC negotiation, which we are presently mediating via email and informal teleconference.

From: Denloye, Aderonke O [mailto:Ade.Denloye@baxalta.com]  
Sent: Monday, May 16, 2016 4:27 PM  
To: Maruna, Thomas  
Cc: Reed, Jennifer  
Subject: Re: Late-Cycle-Meeting Status

could I give you a final decision on this tomorrow 17 May 2016..

Best regards,  
Aderonke Denloye

From: Maruna, Thomas <Thomas.Maruna@fda.hhs.gov>  
Sent: Monday, May 16, 2016 1:21 PM  
To: Denloye, Aderonke O  
Cc: Reed, Jennifer  
Subject: RE: Late-Cycle-Meeting Status

No worries.

Your response by email is sufficient or I can call you now to discuss.

Tom

From: Denloye, Aderonke O [mailto:Ade.Denloye@baxalta.com]  
Sent: Monday, May 16, 2016 4:19 PM  
To: Maruna, Thomas  
Cc: Reed, Jennifer  
Subject: Re: Late-Cycle-Meeting Status

Sorry I just saw your message..is this meeting still on for 3:30pm

Best regards,  
Ade

From: Maruna, Thomas <Thomas.Maruna@fda.hhs.gov>  
Sent: Monday, May 16, 2016 11:02 AM  
To: Denloye, Aderonke O  
Cc: Reed, Jennifer  
Subject: RE: Late-Cycle-Meeting Status

Aderonke,

The Agency would like to hold a brief teleconference with you this afternoon concerning the LCM. We have scheduled this telecon for today at 3:30 pm, ET. Please confirm your availability and provide an appropriate dial-in number.

Should Baxalta inform the Agency concerning its decision on the LCM in advance, there is no need to proceed with this telecon.

Tentative FDA attendees:  
Jennifer Reed, PhD, CBER/OBRR/LPD  
Thomas J. Maruna, MSc, MLS(ASCP), CBER/OBRR/IO/ RPMS

Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH  
Lieutenant, U.S. Public Health Service  
Senior Regulatory Management Officer  
FDA/CBER/OBRR/IO  
thomas.maruna@fda.hhs.gov  
Office: (240) 402-8454

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From: Maruna, Thomas  
Sent: Monday, May 16, 2016 12:20 PM  
To: 'Denloye, Aderonke O'  
Subject: RE: Late-Cycle-Meeting Status  
Importance: High

Aderonke,

I am just following up on this query.

Tom

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From: Maruna, Thomas  
Sent: Friday, May 13, 2016 2:56 PM  
To: 'Denloye, Aderonke O'  
Subject: Late-Cycle-Meeting Status  
Importance: High

Aderonke,

The review division does not believe that the Late-Cycle-Meeting is necessary at this time and that Baxalta is cognizant of the current review status.

The outstanding items to date include the follow-up request for information (in reference to our May 3rd RFI) just sent to you on May 13, 2016 at 2:48 pm, ET and the outstanding PMC negotiation. Note: we are preparing a response to Baxalta's May 9th response to our proposed PMC's, which will be transmitted to you either by this afternoon or early Monday.

We believe these items may be resolved via our continued correspondence through email and amendments.

Does Baxalta concur, or does Baxalta wish to proceed with the Late-Cycle-Meeting scheduled

for next week?

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH  
Lieutenant, U.S. Public Health Service  
Senior Regulatory Management Officer  
Food and Drug Administration  
Center for Biologics Evaluation and Research  
Office of Blood Research and Review  
10903 New Hampshire Ave.  
Silver Spring, MD 20993  
thomas.maruna@fda.hhs.gov  
O: (240) 402-8454  
www.usphs.gov

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