

From: [Wood, Lorraine](#)
To: [MaryAnn Lamb](#)
Subject: RE: FOLLOW UP Re: Mid-Cycle Communication for BLA 125644 HAS 5% and 25%
Date: Monday, June 12, 2017 6:25:00 PM
Attachments: [image001.png](#)
[BPL BLA 125644 Mid-Cycle Telecon Agenda .pdf](#)

Hello Mary Ann,

Attached is the Mid-Cycle Telecon Agenda.

Please let me know if you have any questions.

Thanks
Lorraine

Lorraine D. Wood, MS, MLS(ASCP)^{CM}

Regulatory Project Manager

Center for Biologics Evaluation and Research
Office of Blood Research and Review
U.S. Food and Drug Administration
Tel: 240-402-8439
lorraine.wood@fda.hhs.gov



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From: MaryAnn Lamb [<mailto:MaryAnn.Lamb@bpl-us.com>]
Sent: Monday, June 12, 2017 3:11 PM
To: Wood, Lorraine
Subject: Re: FOLLOW UP Re: Mid-Cycle Communication for BLA 125644 HAS 5% and 25%

Hi Lorraine,

I am following up to see if the agenda for the telecon with BPL is available yet along with any specific questions or additional requests for information. Thank you I advance for providing that ahead of the meeting so that BPL can have the appropriate people on the call.

Best Regards,
Mary Ann

Mary Ann Lamb, PhD
US Agent for BPL
Maryann.Lamb@bpl-us.com
919 417-4432

From: Wood, Lorraine <Lorraine.Wood@fda.hhs.gov>
Sent: Wednesday, June 7, 2017 2:39:42 PM
To: MaryAnn Lamb
Subject: RE: FOLLOW UP Re: Mid-Cycle Communication for BLA 125644 HAS 5% and 25%

Hi MaryAnn,

Thank you for confirming the teleconference date and supplying the dial-in information. The telecon agenda will be submitted to you no later than COB Monday June 12, 2017.

Please contact me if you have any questions.

Sincerely,
Lorraine

Lorraine D. Wood, MS, MLS(ASCP)^{CM}
Regulatory Project Manager

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From: MaryAnn Lamb [<mailto:MaryAnn.Lamb@bpl-us.com>]
Sent: Wednesday, June 07, 2017 10:57 AM
To: Wood, Lorraine
Subject: RE: FOLLOW UP Re: Mid-Cycle Communication for BLA 125644 HAS 5% and 25%

Hi Lorraine,

I have confirmed that BPL can participate in the telecon at the time you have proposed:

11:00 am to 12:00 pm EDT (4:00 to 5:00 UK time).

Dial-In Information:

Toll Free US: (877) 367 6487

Participant code: (b) (4)

Please contact me if you have any questions.

Best Regards,
Mary Ann

Mary Ann Lamb, Ph.D.
Regulatory Consultant
US Agent for BPL, Ltd.
Bio Products Laboratory USA, Inc
Email: maryann.lamb@bpl-us.com
Telephone: (919) 417-4432
Fax: (919) 354-8404

From: Wood, Lorraine [<mailto:Lorraine.Wood@fda.hhs.gov>]
Sent: Wednesday, June 07, 2017 8:18 AM
To: MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>
Subject: Re: FOLLOW UP Re: Mid-Cycle Communication for BLA 125644 HAS 5% and 25%

Hello MaryAnn,

Please let me know if Wednesday June 14, 11:00 am to 12:00 pm EDT is ok with BPL to have the telecon.

Thanks
Lorraine

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: MaryAnn Lamb
Sent: Tuesday, June 6, 2017 9:41 AM
To: Wood, Lorraine

Subject: FOLLOW UP Re: Mid-Cycle Communication for BLA 125644 HAS 5% and 25%

Hi Lorraine,

I am following up to see if you have been able to identify a date/time for the Mid Cycle Communication with BPL that works for you and the FDA review team and that is within business hours in the UK (scheduling the telecon between the hours of 8:00 am to Noon EDT will ensure that it takes place before the close of business in the UK).

Thank you again for your management of the review of BPL's BLA for their Albumin (Human) product.

Please feel free to call me if you have any questions about BPL's availability for the telecon.

Best Regards,
Mary Ann

Mary Ann Lamb, Ph.D.
Regulatory Consultant
US Agent for BPL, Ltd.
Bio Products Laboratory USA, Inc.
Email: maryann.lamb@bpl-us.com
Telephone: (919) 417-4432
Fax: (919) 354-8404

From: MaryAnn Lamb
Sent: Friday, June 02, 2017 11:13 AM
To: 'Wood, Lorraine' <Lorraine.Wood@fda.hhs.gov>
Subject: RE: Mid-Cycle Communication for BLA 125644 HAS 5% and 25%

Could you do a later time on Thursday, June 8? I am traveling that morning and will not land until 11:30 am EDT. Could you do Noon to 1:00 pm EDT (5:00 to 6:00 pm UK time) on Thursday, June 8 or could the telecon be postponed until the following week and hold it on Monday, June 12 or Tuesday, June 13. Postponing until next week for probably be best if possible since if my flight is delayed I would miss the call on Thursday, June 8

Best Regards,
Mary Ann

From: Wood, Lorraine [<mailto:Lorraine.Wood@fda.hhs.gov>]
Sent: Friday, June 02, 2017 10:12 AM
To: MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>

Subject: RE: Mid-Cycle Communication for BLA 125644 HAS 5% and 25%

Hi MaryAnn,

I will be in training early in the day on June 7. We can hold the telecon on Thursday June 8, 2017 11:00 am to 12:00 pm EDT.

Please let me know if that time works for BPL.

Thanks

Lorraine

Lorraine D. Wood, MS, MLS(ASCP)^{CM}

Regulatory Project Manager

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From: MaryAnn Lamb [<mailto:MaryAnn.Lamb@bpl-us.com>]

Sent: Friday, June 02, 2017 9:34 AM

To: Wood, Lorraine

Subject: RE: Mid-Cycle Communication for BLA 125644 HAS 5% and 25%

Importance: High

Hi Lorraine,

I have talked with BPL and they have asked if it is possible to hold the teleconference earlier in the day since 2:00 to 3:00 pm EDT is 7:00 to 8:00 pm in the UK. BPL prefers holding the teleconference sometime between 11:00 am and 1:00 pm EDT (between 4:00 pm and 6:00 pm UK time) however BPL realizes that this time is in the middle of FDA's day and may conflict with lunch. BPL therefore is also willing to hold the teleconference as early as 8:00 am EDT and any time forward up until 1:00 pm EDT (1:00 pm UK time up to 6:00 pm UK time)

If it is necessary to keep the original proposed time, BPL can have the appropriate people call in remotely however with multiple remote locations it may compromise the sound quality on the call.

Please let me know if the time for the teleconference can be changed.

Best Regards,
Mary Ann

Mary Ann Lamb, Ph.D.
Regulatory Consultant
US Agent for BPL, Ltd.
Bio Products Laboratory USA, Inc
Email: maryann.lamb@bpl-us.com
Telephone: (919) 417-4432
Fax: (919) 354-8404

From: Wood, Lorraine [<mailto:Lorraine.Wood@fda.hhs.gov>]
Sent: Thursday, June 01, 2017 8:27 AM
To: MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>
Subject: Mid-Cycle Communication for BLA 125644 HAS 5% and 25%
Importance: High

Dear Dr. Lamb,

Please let me know if BPL is available for the Mid-Cycle Teleconference on June 7, 2017, 2:00 to 3:00 pm EDT for BLA 125644/0 Human Albumin Solution (HAS) 5% and 25%.

Thank you
Lorraine

Lorraine D. Wood, MS, MLS(ASCP)^{CM}
Regulatory Project Manager

Center for Biologics Evaluation and Research
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