

From: Thompson, Edward
Sent: Monday, September 22, 2014 2:15 PM
To: Steve McGregor
Subject: RE: CRMTS#9527 BLA STN 125426/0--Cancelation of Type A Meeting for IXINITY CRL

Dear Steve,

Acknowledge receipt of your message to accept the FDA response to your questions and the meeting for September will be cancelled.

Sincerely,
Ed

Edward Thompson
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From: Steve McGregor [mailto:smcgregor@ebsi.com]
Sent: Monday, September 22, 2014 2:00 PM
To: Thompson, Edward
Subject: CRMTS#9527 BLA STN 125426/0--Cancelation of Type A Meeting for IXINITY CRL

Good afternoon Ed,

With the receipt of the revised response from the FDA on Question #5, we find the responses to the questions raised in our Type A meeting request (request and meeting package dated August 20, 2014) to be sufficiently clear to obviate the need for further discussion and therefore do not need to proceed with the teleconference.

Please accept this email as notification of our request to cancel the teleconference that was scheduled for September 23, 2014.

Please let me know if you require further information or a formal notification of the meeting cancelation through a letter/submission to the BLA.

Best regards,
Steve

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