

**From:** Thompson, Edward  
**Sent:** Thursday, September 18, 2014 5:37 PM  
**To:** 'Steve McGregor (smcgregor@ebsi.com)'  
**Subject:** CRMTS#9527 \_\_STN 125426/0\_\_ FDA Response Memo\_\_ September 23, 2014 Type A Teleconference

**Importance:** High

**Contacts:** Steve McGregor

**SUBJECT:** FDA Response to Cangene Corporation (Emergent BioSolutions) Questions

Dear Mr. McGregor:

Although we continue to reserve September 23, 2014, at 3:15 p.m. to 4:45 p.m. for a teleconference with you regarding this product, if you find that our attached responses and advice are sufficiently clear and complete to obviate the need for further discussion, please inform us in writing as soon as possible so that we may clear the meeting time. These responses would then become the official FDA responses to your questions.

Alternatively, if you have questions regarding specific responses or advice, please inform us so that the appropriate members of the review team can provide clarification during the reserved meeting time. Note that if there are any major changes to your development plan, the purpose of the meeting, or the questions based on our pre-meeting (preliminary) responses, we may not be prepared to discuss and/or to reach agreement on such changes at the meeting although we will try to do so if possible.

Please include a reference to CRMTS #9527 in your future submissions related to the subject product.



CRMTS#9527.ST...

Please note that this meeting is to provide clarification to Cangene Corporation (Emergent BioSolutions) for the FDA response to your questions submitted in your meeting package received on August 20, 2014.

Please contact me if you require additional information to these instructions,

Sincerely,  
Edward Thompson  
Regulatory Project Manager  
FDA/CBER

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