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Subject: STN 125603 483 Responses
Date: Wednesday, August 31, 2016 9:15:00 AM

APPROVED

By Patrick S. Riggins at 9:18 am, Aug 31, 2016

Margarita,

I am sorry for any confusion regarding where to submit the 483 responses for items that are not normally included in the BLA. As we had previously informed you, they do indeed need to be submitted to the BLA as amendments. They should be included in Module 1, specifically under section 1.11 information amendment: information not covered under Modules 2-5. Just be sure to label them as responses to 483 observations. If you have any further questions about this, do not hesitate to let me know.

Regards,

Pat Riggins

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