

**From:** [James Maloney](#)  
**To:** [Riggins, Patrick](#)  
**Subject:** RE: 125590/0.42 Information Request  
**Date:** Monday, November 5, 2018 5:06:46 PM  
**Attachments:** [1.11.1 IR 0044.pdf](#)  
[Lot Release Protocol RI-002.pdf](#)  
[RI002 BLA 356h 0044.pdf](#)  
[RI-002 BLA Cover Letter 0044.pdf](#)

**APPROVED**

*By Patrick S. Riggins, PhD at 5:08 pm, Nov 16, 2018*

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Hi Dr. Riggins,

Please see attached for our response to the below Information Request. This was also submitted via the Gateway today.

Please note that, along with this response, ADMA is requesting an urgent meeting with the Review Division to discuss this Agency request as well as the request dated November 2. Further detail is provided in the cover letter.

I will also follow up with you via phone.

Best Regards,

Jim

James Maloney  
Senior Director, Regulatory Affairs



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**From:** Riggins, Patrick [mailto:Patrick.Riggins@fda.hhs.gov]  
**Sent:** Tuesday, October 30, 2018 10:59 AM  
**To:** James Maloney  
**Subject:** 125590/0.42 Information Request

Jim,

I have an information request for you below. Please confirm receipt of this message and further please submit your response by next Tuesday November 6, 2018 at noon.

1. Have you submitted a revised lot release protocol? If so where can it be found. If not please do so.

Regards,  
Pat Riggins

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