

From: [James Maloney](#)
To: [Riggins, Patrick](#)
Subject: RE: 125590/0/42 Information Request
Date: Wednesday, October 31, 2018 4:54:04 PM
Attachments: [1.11.1 IR final 29Oct2018.pdf](#)
[RI002 BLA 356h 0043 signed.pdf](#)
[RI-002 BLA Cover Letter 0043 signed.pdf](#)

APPROVED

By Patrick S. Riggins, PhD at 4:32 pm, Nov 16, 2018

Dr. Riggins,

Please see attached for our response to the information request below which will also be submitted via the Gateway today. Please let me know if you have any questions related to this submission.

Best Regards,

Jim

James Maloney
Senior Director, Regulatory Affairs



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From: Riggins, Patrick [mailto:Patrick.Riggins@fda.hhs.gov]
Sent: Wednesday, October 24, 2018 3:36 PM
To: James Maloney
Subject: 125590/0/42 Information Request

Jim,

I have the following information request. Please confirm your receipt of this request and also please send you response by next Wednesday, October 31, 2018.

1. Please confirm whether Immune Globulin Intravenous (human, RI-002, has been approved or marketed in any country. Please also supply any available post-marketing data.

Any questions, do not hesitate to let me know.

Regards,

Pat Riggins

Patrick S. Riggins, PhD
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