

From: [Gildner, Jean](#)
To: [Janice Castillo \(jcastillo@Portola.com\)](mailto:jcastillo@Portola.com)
Subject: BLA 125586 Postmarketing Requirement
Date: Thursday, April 26, 2018 4:48:08 PM
Attachments: [image001.png](#)

Dear Janice,

A review the recent submission concerning the RCT shows that Portola is referring to this requirement as a Postmarketing Study Commitment (PMC). Please submit this document as a Postmarketing Requirement(PMR). Please see the headline of the cover letter below. Please ensure that this study is referred to as a PMR throughout all documents. I appreciate you attending to this request as soon as possible. Please acknowledge receipt of this email. As always if you have any questions please feel free to contact me.

**RE: Investigational New Drug: AndexXa® (andexanet alfa)
BLA 125586 / SN0129
Response to 24 April 2018 BLA Resubmission Information Request:
Postmarketing Study Commitment Protocol
(Randomized Control Trial (RCT) Protocol (18-513) and Study Milestones)**

Sincerely, Jean

Jean F. Gildner MSHS, MT (ASCP)

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