From:	Gildner, Jean
To:	Janice Castillo (jcastillo@Portola.com)
Subject:	BLA 125586 Information Request
Date:	Thursday, December 07, 2017 7:30:53 AM
Attachments:	IR for STN 125586.docx image001.png image002.jpg image003.jpg image004.jpg image005.jpg image006.jpg

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Dear Janice,

Please see the following information request. We are asking that you respond on or before December 21, 2017. Please acknowledge receipt of this email.

As always if you have any questions please feel free to contact me.

Sincerely, Jean

Jean F. Gildner MSHS, MT (ASCP)

Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-8296
jean.gildner@fda.hhs.gov

7 December 2017

IR for STN 125586/0 - PORTOLA PHARAMCEUTICALS' BLA for Andexanet Alfa

1. Regarding sections 3.2.S.7.2 and 3.2.P.8.2, and your post-approval stability protocol and stability commitment for commercial lots to place (b) (4) at least (b) (4) Final Drug Product (FDP) lot (b) (4) on stability study, please revise the protocols to include the following time-points: 3, 6, and (b) (4) months.

2. Please provide updated results from the ongoing stability studies, which should include 24 months of data for (b) (4); and FDP lots (b) (4). If there are out-of-specification (OOS) results, please provide the reasons for the OOS.

3. Please provide the investigation reports for the two OOS results in (b) (4) by the (b) (4) method for (b) (4).

Please respond by December 21, 2017.