

**From:** Maruna, Thomas  
**Sent:** Wednesday, April 06, 2016 4:00 PM  
**To:** 'Janice Castillo'  
**Subject:** Information Request (Statistical) - BLA 125586.0 - Please respond by April 20, 2016

Portola Pharmaceuticals Inc.  
Attention: Ms. Janice Castillo  
April 6, 2016  
Sent by email

Dear Ms. Castillo:

We are reviewing your December 17, 2015 biologics license application (BLA) for the following:

<b>STN</b>	<b>Name of Biological Products</b>
125586/0	Coagulation Factor Xa (Recombinant), Inactivated

We determined that the following information is necessary to continue our review:

1. If you agree, please correct the following typos or errors:
  - In Table 5 on page 61 of Study Report 14-503, the number of subjects should be 23 instead of 24 for the per-protocol population in the ANDEXXA group in Part 2.
  - In Table 7 on page 66 of Study Report 14-503, the total number of subjects in Part 2 should be 31 instead of 32.
  - In Table 9 on page 61 of Study Report 14-504, the mITT set for the placebo group in Part 1 actually included 13 subjects, rather than 14.
  - In Table 11 on page 67 of Study Report 14-504, the values for the placebo group in Part 1 were in fact based on 13 subjects rather than 14: one subject ((b) (6)) with a missing outcome was excluded from the analysis.
2. In Part 1 of Study 14-504, Subject ((b) (6)) from the ANDEXXA group seemed to have different values on all efficacy endpoints, compared to other subjects in the same group. Please provide an explanation.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your responses as an amendment to this file by April 20, 2016.

The action due date for these files is August 17, 2016.

If you have any questions, please contact me.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH

Lieutenant, U.S. Public Health Service

Senior Regulatory Management Officer

Food and Drug Administration

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