

APPROVED

By Jean Gildner at 12:18 pm, Sep 25, 2017

From: [Gildner, Jean](#)
To: [Janice Castillo \(jcastillo@Portola.com\)](mailto:jcastillo@Portola.com)
Subject: BLA 125586 Information Request
Date: Thursday, September 21, 2017 5:02:12 PM
Attachments: [image001.png](#)

Dear Janice,

Please find an Information Request. Please let me know if you are not able to meet the deadline.

Please provide the following information by October 3, 2017

- 1) Datasets for Subject (b) (6) are missing. Please include this subject's information in the datasets
- 2) For the ANNEXA-4 (14-505) study, the submitted datasets include 101 subjects in the Complete Safety Population (data cutoff date 20 September 2016). However, results with 185 subjects in the DSUR Safety Population (data cutoff date 20 April 2017) are reported in the "14-505 Clinical Study Report Addendum" in the BLA resubmission but not the associated datasets. Please provide datasets based on the cut-off date of 20 April 2017 used in the DSUR. In addition, in the new datasets, please include two variables: one to identify subjects evaluable for efficacy, and the other one to indicate the reason if not evaluable for efficacy.
- 3) Please ensure that the AE data tables include any AE (irrespective of attribution) including death from all causes for all subjects who received one dose of andexanet based on the data cut-off date of April 20, 2017.
- 4) Please include CRFs for all subjects who received one dose of andexanet based on the data cut-off date of April 20, 2017

Please acknowledge receipt of this email.

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



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM

IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.