



Our STN: BL 125586/0

PROPRIETARY NAME ACCEPTANCE

Portola Pharmaceuticals, Inc.
Attention: Ms. Janice Castillo
270 East Grand Avenue
South San Francisco, CA 94080

Dear Ms. Castillo:

We have reviewed your submission dated February 1, 2016, to your biologics license application (BLA) for Coagulation Factor Xa (Recombinant), Inactivated requesting a proprietary name review.

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, ANDEXXA, is acceptable.

If you have any questions, please contact LT Thomas J. Maruna, USPHS, MSc, MLS(ASCP), CPH at (240) 402-8454 or thomas.maruna@fda.hhs.gov.

Sincerely,

Howard Chazin, MD, MBA
Acting Director
Division of Hematology Clinical Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research