



SUPPLEMENT APPROVAL
December 31, 2018

Our STN: BL 125586/27

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

Dear Ms. Castillo:

We have approved your request dated August 30, 2018, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for coagulation factor Xa (recombinant), inactivated-zhzo to include (1) the new manufacturing process (Generation 2) for the (b) (4); (2) (b) (4) as manufacturer of Generation 2^{(b) (4)}; and (3) a new Drug Product (DP) dosage strength of 200 mg, manufactured by (b) (4) for the Generation 2^{(b) (4)}.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Peter W. Marks
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Digitally signed by Peter W. Marks -S
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ou=FDA, ou=People, cn=Peter W. Marks -S,
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Date: 2018.12.31 11:00:09 -05'00'

Peter W. Marks, MD, PhD
Director
Center for Biologics Evaluation and Research

Enclosed: Package Insert