

STN 1255060 Information Request .txt

From: Rana, Prati bha
Sent: Tuesday, August 11, 2015 12:10 PM
To: MaryAnn Lamb
Subject: STN 125506/0 Information Request

Our Reference: STN 125506
Bio Products Laboratory

Dear Dr. Lamb:

We are reviewing your biologics license application (BLA) for Coagulation Factor X (Human) and have the following information request.

1. FDA maintains that the data submitted in the biologics license application for Coagulation Factor X (Human) are insufficient to support a general indication for perioperative management. The submission lacks data with regard to perioperative management of bleeding in patients with moderate and severe deficiency undergoing major surgery. Therefore, it would be misleading in the absence of these data to revise the indication to state that there is limited data in patients with moderate and severe deficiency, as proposed by you in the July 31, 2015 teleconference. Instead, we propose the following clarifying revision: Coagadex, a plasma-derived blood coagulation factor X concentrate, is indicated in adults and children (aged 12 years and above) with hereditary Factor X deficiency for:

- * On-demand treatment and control of bleeding episodes
- * Perioperative management of bleeding in patients with mild hereditary Factor X deficiency.

Perioperative management of bleeding in major surgery in patients with moderate and severe hereditary Factor X deficiency has not been studied.

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

Please submit your responses as an amendment to this file referencing the date of this request.

The action due date for this file is October 27, 2015.

Please call me or contact me at prati bha.rana@fda.hhs.gov
Prati bha

Prati bha Rana, M. S.
Regulatory Project Manager

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