Our STN: BL 125506/164

SUPPLEMENT APPROVAL
PMC FULFILLED
April 14, 2023

Bio Products Laboratory Limited
Attention: Chaaya Ganorkar, PhD
302 East Pettigrew Street, Suite C-190
Durham, NC 27701

Dear Dr. Ganorkar:

We have approved your request received July 22, 2022 to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Coagulation Factor X, (human) [Coagadex] to expand the indication for perioperative management of bleeding to include patients with severe hereditary Factor X deficiency based on submission of the final study report for Study TEN06, intended to fulfill your Postmarketing Commitment #1.

The review of this supplement was associated with the following National Clinical Trial NCT number: 03161626.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling Package Insert submitted under amendment 10, dated March 28, 2023.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on March 28, 2023. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.
The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125506/0 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your post-marketing commitment (PMC) #1 identified in the October 20, 2015 approval letter for BLA STN BL 125506/0 for Coagulation Factor X, (human). The commitment addressed in this submission is as follows:

1. BPL commits to evaluate the safety and efficacy of COAGADEX for perioperative management in patients with moderate to severe hereditary Factor X deficiency undergoing major surgical procedures in Study TEN06, *A post-marketing registry study of perioperative management of moderate to severe hereditary factor X deficient patients receiving Coagadex (human factor X concentrate) for major surgical procedures.*

Final protocol submission date: April 30, 2016
Trial completion date: December 31, 2021
Final Report Submission date: September 30, 2022

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because the biological product for this indication has an orphan drug designation, you are exempt from this requirement.

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

Sincerely,

Tejashri Purohit-Sheth, MD
Acting Director
Division of Clinical Evaluation Hematology
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research