Our STN: BL 125234/336

SUPPLEMENT APPROVAL
August 25, 2021

Baxalta US, Inc.
Attention: Tabitha Yu
4501 Colorado Blvd
Los Angeles, CA 90039

Dear Ms. Yu:

We have approved your request submitted and received on April 30, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Protein C Concentrate (Human) [CEPROTIN] to transfer the (b) (4) immunoaffinity gel preparation steps to (b) (4) (b) (4) in (b) (4), as an alternate process; remove mouse minute virus testing at the (b) (4) production step; use a new container closure system for 1000 IU CEPROTIN at (b) (4) in (b) (4); and update the CEPROTIN package insert.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 4, dated August 13, 2021.

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 August 13, 2021. 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 125234/0 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)).

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

Sincerely,

Basil Golding, MD
Director
Division of Plasma Protein Therapeutics
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research