Our STN: BL 125287/459

SUPPLEMENT APPROVAL
September 15, 2021

CSL Behring GmbH
Attention: Trung Ly
CSL Behring, LLC
1020 First Avenue
P.O. Box 61501
King of Prussia, PA 19406

Dear Mr. Ly:

Please refer to your supplement to your Biologics License Application (BLA) submitted on August 31, 2020, and received on September 1, 2020, under section 351(a) of the Public Health Service Act (PHS Act) for C1 Esterase Inhibitor (Human) to introduce the inclusion of an administration kit consisting of a silicon-free syringe, winged infusion set, and an alcohol swab for the Berinert 500 combination product.

We also refer to our supplement approval letter dated March 1, 2021, which contained the following error:

- Reference to labeling was not included in the supplement approval letter.

This replacement approval letter incorporates the correction of the error. The effective approval date is September 15, 2021.

We have approved your request submitted August 31, 2020, received September 1, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for C1 Esterase Inhibitor (Human) to introduce the inclusion of an administration kit consisting of a silicon-free syringe, winged infusion set, and an alcohol swab for the Berinert 500 combination product.

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 4 dated September 7, 2021,and the draft carton and container labels, submitted on August 31, 2020.

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 September 7, 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.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 31, 2020, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125287 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.

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

Sincerely,

for

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