Our STN: BL 125384/107

SUPPLEMENT APPROVAL
June 9, 2020

Kedrion S.p.A.
Attention: Mr. Grexan Wulff
400 Kelby Street, 11th Floor
Fort Lee, NJ 07024

Dear Mr. Wulff:

We have approved your request submitted and received January 28, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Albumin (Human) to revise the Package Insert (PI), vial labels, cartons and Structured Product Labeling (SPL) in compliance with the Pregnancy and Lactation Labeling Rule (PLLR) and Drug Supply Chain Security Act (DSCSA).

We hereby approve the draft package insert labeling and the draft carton and container labeling submitted on May 22, 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. 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.

PACKAGE AND CONTAINER LABELS

Please electronically submit final printed package and container labels that are identical to the package and container labels submitted on May 22, 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 125384 at the time of use (prior to marketing) 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.

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)).

In response to the COVID-19 public health emergency, CBER's Document Control Center (DCC) will not process any submission received by mail or courier including submissions provided on paper and electronic media (e.g., CDs, USB) after Wednesday, April 29, 2020, until further notice. Submissions previously submitted by mail can still be submitted electronically using the Electronic Submissions Gateway (ESG) (under 10GB) or in some cases via email (under 150MB). CBER strongly encourages sending submissions through the ESG, FDA's preferred secure method of transmission. Instructions for setting up an ESG account can be found at https://www.fda.gov/industry/electronic-submissions-gateway.

Submissions regarding this file may also be submitted electronically as an unstructured Portable Document File (PDF) via email at CBERDCC_eMailSub@fda.hhs.gov. We will accept submissions through this email option only during the COVID-19 public health emergency. For additional information regarding CBER operations during this public health emergency, please see the CBER COVID -19 CBER Regulated Biologics page found at https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics.

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

Sincerely,

Orieji Illoh, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research