Our STN: BL 103777/5429

SUPPLEMENT APPROVAL
May 30, 2019

Kedrion Biopharma Inc.
Attention: Wei (Helena) Tong, PhD
Director of Regulatory Affairs
400 Kelby Street, 11th Floor
Fort Lee, NJ 07024

Dear Dr. Tong:

We have approved your request submitted December 14, 2018, received December 17, 2018, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Rho(D) Immune Globulin (Human) [RhoGAM and MICRhoGAM], to include changes to the Prescribing Information (PI) to align the HIGHLIGHTS section and Section 5.1 of the FULL PRESCRIBING INFORMATION (FPI) and to provide minor editorial revisions.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 5429, December 14, 2018.

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.

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,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation and
Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research