Our STN: BL 125416/203

SUPPLEMENT APPROVAL
October 1, 2024

Octapharma Pharmazeutika Produktionsges m.b.H.
Attention: Sergio Alegre
Octapharma USA Inc.
117 West Century Road
Paramus, NJ 07652

Dear Sergio Alegre:

We have approved your request received July 30, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Pooled Plasma (Human), Solvent/Detergent Treated to include TRALI (transfusion related acute lung injury) in the post-marketing experience section of the Octaplas (Pooled Plasma (Human), Solvent/Detergent Treated) prescribing information (PI).

We have reviewed your proposal to add transfusion-related acute lung injury to the table in section 6.2 of the label to harmonize labels, based on input from European regulators. We agree with adding transfusion-related acute lung injury. However, since this entity is most recognized by clinicians as the acronym TRALI, we prefer you add the following to the table: “Transfusion-related acute lung injury (TRALI).”

LABELING

We hereby approve the draft package insert labeling and the draft container labeling submitted on July 30, 2024.

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 July 30, 2024. 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.

CONTAINER LABELS

Please electronically submit final printed container labels identical to the container labels submitted on July 30, 2024, 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 125416 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the change approved today.

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

Sincerely,

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