Our STN: BL 125416/167

SUPPLEMENT APPROVAL
PMR FULFILLED
February 25, 2021

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
Octapharma USA, Inc.
117 West Century Road
Paramus, NJ 07652

Dear Mr. Ammons:

We have approved your request submitted and received October 30, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Pooled Plasma (Human), Solvent/Detergent Treated to provide revised labeling and the LAS-213 final study report for the pediatric assessment.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 4, dated February 2, 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 February 2, 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 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.

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.

FULFILLED POSTMARKETING REQUIREMENT

This submission fulfills your postmarketing requirement PMR# 2 identified in the January 17, 2013, approval letter for BLA STN BL 125416 for Pooled Plasma (Human), Solvent/Detergent Treated. The requirement addressed in this submission is as follows:

2. A non-interventional, open-label, multicenter, clinical study to investigate safety, tolerability and efficacy of Octaplas™ in the management of pediatric patients <16 years old who require therapeutic plasma exchange

   Final Protocol Submission: August 2013
   Study Completion Date: March 2017
   Final Report Submission: October 31, 2017

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

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