Our STN: BL 125416/140

SUPPLEMENT APPROVAL
PMR FULFILLED
March 29, 2019

Octapharma Pharmazeutika Produktionsges m.b.H
Attention: Mr. Stanley Ammons
Octapharma USA Inc.
121 River Street, Suite 1201
Hoboken, NJ 07030

Dear Mr. Ammons:

We have approved your request submitted and received September 28, 2018, 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 a labeling update pertaining to PMR #1: An open-label, multicenter, clinical study to investigate the safety, tolerability and efficacy of Octaplas™ in the management of pediatric patients < 16 years old who require replacement of multiple coagulation factors.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 5, dated March 25, 2019.

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.

All final labeling should be submitted as Product Correspondence to this BLA 125416 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 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)).

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing requirement PMR #1 identified in the January 17, 2013, approval letter for BLA 125416 for Pooled Plasma (Human), Solvent/Detergent Treated. The requirement addressed in this submission is as follows:

PMR 1: An open-label, multicenter, clinical study to investigate safety, tolerability and efficacy of Octaplas™ in the management of pediatric patients <16 years old who require multiple plasma coagulation factors.

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 ages <16 years who require multiple plasma coagulation factors for this application.

We are deferring submission of your pediatric study for ages ≥2 years to ≤20 years who require therapeutic plasma exchange until October 31, 2020.

Your deferred pediatric study required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) is a required postmarketing study. The status of this postmarketing study must be reported according to 21 CFR 601.28 and section 505B(a)(3)(B) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of the approval of BLA 125416 until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. This required study is listed below:

PMR 2: Deferred pediatric study under PREA for the treatment of pediatric patients ≥2 years to ≤20 years old with thrombotic thrombocytopenic purpura (TTP) who require therapeutic plasma exchange.

Final Protocol Submission: August 2013

Study Completion Date: March 2017

Final Report Submission: October 31, 2020

Submit the protocol to your IND 13956, with a cross-reference letter to BLA 125416 explaining that this protocol was submitted to the IND.

Submit final study reports to BLA 125416. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated as:

- **Required Pediatric Assessment**

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

Sincerely,

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