CLINICAL MEMORANDUM

From	Laurence Landow MD, Medical Officer, CRS/DBCD/OBRR
To	Orieji Illoh MD, Division Director, CRS/DBCD/OBRR
And	Wendy Paul MD, Deputy Division Director, CRS/DBCD/OBRR
Through	Salim Haddad MD, Team Lead, CRS/DBCD/OBRR
Re	Prior Approval Supplement
BLA	125416/140
Product	Octaplas (solvent detergent treated human plasma)
Sponsor	Octapharma USA Inc

EXECUTIVE SUMMARY

This Prior Approval Supplement regards changes to the Octaplas labeling:

1. Inclusion of data derived from pediatric assessment study LAS 212 requested in the BLA approval letter dated January 17, 2013.[1] The final study report has been submitted to FDA under BLA 125416/138 and was found acceptable, and determined to have fulfilled the post marketing requirement (PMR).
2. Update of post marketing experience with information about passive transmission of β-human chorionic gonadotropin following the use of Octaplas (Stohlawetz PJ et al. False-positive pregnancy test after transfusion of solvent/detergent-treated plasma. Transfusion 2017; 57:2965–2968).
3. Editorial modification: Correction of address of Octapharma Stockholm manufacturing site.

Reviewer assessment

1. Following an interactive process, the latest revision to the PI reflects FDA's comments and is acceptable.
2. The revised PI now includes, in addition to the four premarketing BLA studies already described in section 14 of the PI (three studies conducted in subjects and one study conducted in volunteers), the recently completed postmarketing pediatric PMR study LAS 212 submitted under 125416/138. The BLA studies were not powered for efficacy and thus, would ordinarily be found in section 6.1 (Clinical Trials Experience); however,

[1] "An open-label, multicenter, Post-Marketing Requirement (PMR) study to investigate the safety, tolerability and efficacy of Octaplas in the management of pediatric patients who require replacement of multiple coagulation factors."

the overriding concern of OBRR and the Blood Products Advisory Committee at time of original approval was safety, since the product is derived from S/D treated pooled human plasma. Since prescribers typically focus on clinical study data when reviewing the PI, the original labeling presented this information in section 14.

Recommendation: Approval.