

DMPQ Filing Memo - Hizentra

To: Carolyn Renshaw, Branch Chief, MRBI/DMPQ/OCBQ/CBER
From: Sarah B. Tanksley, Reviewer, MRBI/DMPQ/OCBQ/CBER
Through: Debbie Trout, Team Leader, MRBI/DMPQ/OCBQ/CBER
Subject: Filing Memo for STN 125350/0 for CSL Behring Immune Globulin Subcutaneous (Human) (IGSC) 20% Liquid

Recommendation: I recommend filing this BLA.

Summary: I did not attempt to determine the technical merit of the information during this perfunctory review.

This application included the following sections to be reviewed by DMPQ:

Location	Description of Information
Section 3.2.P	Description of the product and active components
Section 1.12.14	List of other products manufactured
Section 2.3.S.2-2; 3.2.P.3.1	A description of all manufacturing sites (including contract facilities) and floor diagrams
Section 2.3.S.2; 3.2.P.3.3	Methods of manufacture: starting material, reagents, flow charts, process details
Section 3.2.R	Completed batch records
Section 2.3.P.6	Reference standards
Section 3.2.P.7; 2.3.S.6; 2.3.S.2-5.5	Container closure and shipping containers
Section 1.12.14	Environmental Assessment (requesting categorical exclusion)
Section 3.2.A.1	General establishment description
Section 3.2.A.1	Water systems summary, validation, and routine monitoring schedule
Section 3.2.A.1	HVAC description, validation, and plan for routine monitoring
Section 3.2.A.1	Contamination/ Cross-contamination information, including equipment and cleaning

N/A	Lyophilization data
Section 3.2.A.1	Computer systems validation