

**FDA/CBER/OCTGT**  
**Clinical Review of BLA 125585, Amendment 4**  
**Clinical Reviewer: Agnes Lim, M.D.**

**RE:** Name change, from Puget Sound Blood Center (PSBC) to Bloodworks

**Clinical Review of Amendment 4:**

The Applicant submitted an official letter, dated December 15, 2015, to request a name change, from Puget Sound Blood Center (PSBC) to Bloodworks, via Amendment 4 to BLA 125585.

In the letter, the Applicant states, “HPC, Cord Blood ISBT Labels and Accompanying Documentation has been updated to reflect our new name Bloodworks. Please note that NMDP controlled documentation has also been updated to reflect our new name Bloodworks.”

Regulatory Background

PSBC submitted a letter to the FDA Office of Blood Research and Review (OBRR) requesting a legal name change from Puget Sound Blood Center and Program to Bloodworks on November 2, 2015. OBRR approved the name change and issued Bloodworks a new licensed number (U.S. Licensed Number 2042) by letter on November 16, 2015.