



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our STN: BL 101737/5082

November 16, 2015

Puget Sound Blood Center and Program
Attention: Christine L. Donatelli
921 Terry Avenue
Seattle, Washington 98104-1256

Dear Ms. Donatelli:

We have been advised by your letter dated November 2, 2015 that you are requesting to change your legal name from Puget Sound Blood Center and Program operating under U.S. License Number 192 to Bloodworks. Your firm will henceforth be known as Bloodworks operating under your new FDA issued U.S. License Number 2042. You may use your new legal name and U.S. License number in future communications with FDA.

After receipt of this letter, please submit a CBE label supplement with only one example of your FDA previously approved ISBT product labels bearing your new legal name and U.S. License Number.

We will include information contained in the above-referenced supplement in your biologics license application file.

Sincerely yours,

for Richard J. Davey, M.D.

Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics
Evaluation and Research