

**Cara H.Lim**

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**From:** Blood Service Notices and Alerts <hospitalervices@vitalant.org>  
**Sent:** Friday, December 7, 2018 9:58 AM  
**To:** Cara H.Lim  
**Subject:** Blood Service Notice: Reminder - FDA license change

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### Reminder: FDA license change

Dear Cara,

On Nov. 20, we sent you a notice of updates to our product labels, including a move from our legacy FDA license to a new license under the name Vitalant beginning **Dec. 17, 2018**. *(See appendix below for a quick reference chart.)*

### Take action

While we transition, please ensure your processes can accommodate both legacy and new labels.

- You will continue to **see both Blood Systems and Vitalant labels** as we work through our inventory. If you have any questions, feel free to call your local blood center contact.
- The name **Vitalant** with **U.S. License Number 2106** will appear on products collected on or after Dec. 17.
- You will continue to see legacy centers dba Vitalant with the following licenses 1776, 1705, 274 or 1025.

### Other changes beginning Dec. 17

Please note the following changes as we make this transition listed below:

- Current blood product labels contain the statement "Neg for ZIKA by Investigational NAT." Products collected on or after Dec. 17, will no longer contain this statement.
- Blood products collected in states endemic for Babesia, currently have an attached tie tag which states "Neg for Babesia by investigational NAT." Beginning Dec. 17, this statement appears on the product label, thereby eliminating the attached tie tag.
- An updated Circular of Information will be distributed with product deliveries beginning Dec. 17, 2018.

For **regulatory questions**, you may call Director Compliance & Regulatory Affairs Kathleen Hopping at 602.414.3816.

Of course, if your physicians have urgent questions related to transfusion, they may call our **24-hour Transfusion Medicine Hotline for Physicians** at 800.811.2581. Thank you for the opportunity to serve you and your patients.

Sincerely,

**Vitalant**

## Appendix

<b>Manufacturer Name on Blood Product Labels Current</b>	<b>FDA License # Current</b>	<b>Manufacturer Name on Blood Product Labels On 12/17</b>	<b>FDA License # On 12/17</b>
Blood Systems, Inc.	183	Vitalant	2106
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Blood Systems, Inc.	183	Vitalant	2106
Blood Systems, Inc.	183	Vitalant	2106
Blood Systems, Inc.	183	Vitalant	2106
BloodSource, Inc.	1776	BloodSource, Inc. dba Vitalant	1776
LifeShare Community Blood Services	1705	LifeShare Community Blood Services dba Vitalant	1705
Bergen Community Regional Blood Center	274	Bergen Community Regional Blood Center dba Vitalant	274
LifeSource	1025	LifeSource dba Vitalant	1025
LifeSource dba Central Blood Bank	1025	LifeSource dba Vitalant	1025

*Vitalant, formerly known as Blood Systems, also consists of the blood centers formerly known as Blood Centers of the Pacific, BloodSource, Bonfils Blood Center, Central Blood Bank, Community Blood Services, Inland Northwest Blood Center, The Institute for Transfusion Medicine, Lifeblood, LifeShare Community Blood Services, LifeSource, and United Blood Services.*

Date: December 12, 2018

To: Kaiser Permanente NCAL Laboratory Blood Bank Medical Director, Laboratory Administrative Director, Assistant Laboratory Administrative Director Quality, Blood Bank Supervisor

From: TMPG NCAL Laboratory Quality and Compliance

Re: Blood Systems, Inc Name Change on Blood Product Labels, Effective Dec 17, 2018

<b>Situation</b>	<p>Blood Systems, Inc and their affiliated partners are changing the labels on their blood products to reflect their new organization name, currently Blood Systems, Inc. to Vitalant on Dec. 17.</p> <p>This change does not include, or impact blood supplied by the American Red Cross.</p>
<b>Background</b>	<p>The Blood Systems, Inc. supplier represents a nationwide network of many blood centers that are now aligned under a single brand to better serve their customers.</p>
<b>Assessment</b>	<p>The new Vitalant blood supplier name will appear on the upper left area of the blood product label below the donor unit identification number.</p> <p><b><i>There will be no change to laboratory workflow, and no change to the blood administration workflow.</i></b></p> <p>The legacy blood supplier identity will be retained in our laboratory information system and a record of change to the new Vitalant labeling will be retained. Please refer to the table below and blood supplier notification.</p>
<b>Recommendation</b>	<p>This change will take place on Monday, Dec. 17 approximately 10 AM. Both new and old blood supplier labels may be seen during the time of transition.</p> <p>Communication of this change should include Nurses, Physicians and other clinical staff that receive blood products from the transfusion service, transport and/or transfuse blood products to our patients.</p>

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