Canadian Blood Services
Société canadienne du sang

1800 Alta Vista
Ottawa, ON K1G 4J5
T 613.739.2300 F 613.731.1411
www.blood.ca www.sang.ca

2018-08-01
CBS Control #: CBS6212
HPFB File #: C1892-100390
REF: H-1819-OTT

Ms. Victoria Hurlbut
Biologic Products Specialist
Regulatory Operations and Regions Branch
Health Canada
Suite 1625, 16th Floor
1505 Barrington Street
Halifax, Nova Scotia
B3J 3Y6

Dear Ms. Hurlbut:

Re: Further to the Responses to the Health Canada Inspection of Ottawa Operations 2018-06-11 to 2018-06-15

The following are the actions taken by Canadian Blood Services in response to the Health Canada email dated 2018-07-20 requesting additional information for observations to the Exit Notice for Health Canada's Inspection of Ottawa Operations.

Section 61 - Labelling

1. **There is no process in place to ensure the labelled volume of apheresed platelets is accurate. For example, during review of EA 55-18-135185 it was noted that a unit of apheresed platelets was distributed to a hospital with an incorrect volume on the end label. Although the root cause was determined to be associated with an error by the operator performing separation in eProgesa on the platelet unit, there are no other processes or controls in place to verify the volume on the "Work in Process" or final end label is accurate.**

   Canadian Blood Services Response:

   A review of the volumes of all apheresis platelets produced in the last six months indicates that this is the only occurrence of a platelet unit labelled with a default weight of 495 mL. An assessment will be performed by 2018-11-30 to determine if ePROGESA can be configured to prevent any apheresis platelet with a default volume from being end labelled.

   Health Canada Follow-up email dated 2018-07-20:

   1) **Can you confirm that the review performed of the "volumes of all apheresis platelets produced in the last six months" take into account all of the platelet units produced during this period or was the review performed to identify other error/accidents identified that were associated with incorrect volume labels on apheresis platelet units specifically?**

   Canadian Blood Services Response:

   The review included all 18,722 platelets produced within the last 6 months at all sites to confirm the incident identified during the audit was a one-time event at the Ottawa Site and was not a larger issue that was occurring at other sites. The scope of the review was limited to apheresis platelets. The review performed did not include pooled platelets as there is no default weight in eProgesa.

2) **To identify the scope of this issue, did the review performed only include the CBS Ottawa Operations facility or was it performed for all CBS sites who perform these activities?**

Canadian Blood Services Response:

The review included all Canadian Blood Services sites that process apheresis platelets.

3) **Are there other apheresis components that have default volumes set in ePROGESA and were they assessed to determine whether the issues identified with this error/accident are also applicable to these components?**

Canadian Blood Services Response:

The investigation was limited to apheresis platelets as this is the only apheresis product that includes a process for modification due to the removal of an aliquot for bacterial detection. There was an assessment of all other final apheresis (AFFP, Source Plasma and ACD-A AFFP) components and none have a default weight therefore the issues identified with this error /accident are not applicable to these components.

4) **The response is focused on determining an ePROGESA configuration fix. However it was brought to the attention of the site staff that this error/accident actually impacted other regulated activities e.g. end labelling, release and distribution. Do you intend or have you also assessed these activities for potential corrective actions to enhance control?**

Canadian Blood Services Response:

As described above, this was a single event among 18,722 platelet units produced (rate of occurrence of 0.005%). As such a change to other processes has not been deemed necessary.

5) **Do you anticipate the incidence of this type of error/accident to increase with the implementation of Apheresis Plasma Collections on the TRIMA initiative?**

Canadian Blood Services Response:

We do not anticipate an increase in this type of error with the implementation of apheresis plasma collections on the Trima as the process for managing the apheresis components did not change.

If you require clarification or further information, please do not hesitate to contact the undersigned. **Please reference the above CBS control number in any correspondence.**

Sincerely,

Christian Choquet

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affairs
Fax Number: 613-739-2505

cc: Hugo Tremblay
Supervisor – Blood Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch

SL