Canadian Blood Services
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2018-02-06
CBS Control #: CBS6115
HPFB File #: C1892-100390
REF: H-1718-WIN

Ms. Shelley Smyth
Compliance Specialist
Biological Products Compliance Program
Regulatory Operations and Regions Branch
Health Canada
300-391 York Avenue
Winnipeg, Manitoba
R3C 4W1

Dear Ms. Smyth:

Re: Follow-up to Responses to Health Canada Inspection of Licensed Activities at Winnipeg Operations 2017-10-16 to 2017-10-20

The following are the actions undertaken by Canadian Blood Services in response to the Health Canada letter dated 2018-01-26 requesting additional information for observations to the Exit Notice for Health Canada's inspection of Winnipeg Operations.

Section 107 - Investigation and Reporting

1. **There was no Error/ Accident reported to Health Canada relating to the Adverse Transfusion Reactions #40-17-800001AR and #40-17-800002AR that were caused by a transfused double platelet unit that had false negative BacT test results. These adverse transfusion reactions were reported to Canada Vigilance on August 28, 2017.**

   Canadian Blood Services Response:

   40-17-800001AR and 40-17-800002AR were reported on 2017-08-30 as Adverse Transfusion Reactions to the Health Canada Marketed Health Products Safety and Effectiveness Information Bureau, as required by section 110 of the Health Canada, Blood Regulations.

   The request to also report this issue as an Error/Accident creates unnecessary duplicate reporting.

   This item will be brought forward for discussion at the Bilateral Meeting between Health Canada and Blood Operators in December 2017.

   Health Canada Follow-up Letter dated 2018-01-26

   In regards to the response to observation #3 "There was no Error/ Accident reported to Health Canada relating to the Adverse Transfusion Reactions #40-17-800001AR and #40-17-800002AR that were caused by a transfused double platelet unit that had false negative BacT test results. These adverse transfusion reactions were reported to Canada Vigilance on August 28, 2017.", I understand that this issue was brought forward for discussion at

the Bilateral Meeting between Health Canada and Blood Operators that occurred on December 12, 2017, but has not yet been fully resolved.

Copies of these Adverse Reaction reports that were submitted to the Canada Vigilance Program of the Marketed Health Products Safety and Effectiveness Information Bureau were provided during the inspection. We have confirmed with the Canada Vigilance Program that they do not have any further information related to these Adverse Reactions.

In order to proceed with the completion of this inspection, in relation to the response to this observation, please provide the undersigned with a copy of the investigation report related to these adverse reactions that was not yet completed at the time of the inspection. According to CBS staff, the report was not written up yet in CAPA format as the investigation had not been completed by the Component Production department.

Canadian Blood Services Response:

Please find attached a copy of the Investigation Report CAPA# 40-17-101494.

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,

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

Attach