Canadian Blood Services
BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

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2021-12-23
CBS Control #: CBS6602
HPFB File #: C1892-100390
REF: H-2122-EDM-W-Follow-Up

Erin Vandendyck
Regional Regulatory Compliance & Enforcement Officer, GMP Inspection West
Regulatory Operations and Enforcement Branch,
Health Canada

Dear Erin Vandendyck:

Re: Further to the Responses to Health Canada Inspection of Wholesale Activities at Edmonton Operations from 2021-10-12 to 2021-10-15

The following are the actions undertaken by Canadian Blood Services in response to the Health Canada letter dated 2021-12-09, requesting additional information for the observation to the Exit Notice from Health Canada's Inspection of wholesale activities at Edmonton Operations.

C.02.024 - Records

1. The firm was unwilling and/or unable to provide sufficient information to verify compliance on their self-inspection program.

1. Records for the self-inspection program were incomplete or missing. The first and third pages of the 2018 self-inspection report were reviewed. At the time of the inspection, the 2021 self-inspection report was still in progress. The records for the results of their self-inspection program, evaluation and conclusions, and corrective measures implemented were not available.

During the audit of the wholesale activities in Edmonton the following documents relating to the 2018 self-inspection were requested and reviewed:

- *the standard operating procedures,*
- *the audit plan,*
- *the audit checklist,*
- *the executive summary,*
- *the audit report signature page, and*
- *a listing of the number of observations and their criticality.*

In addition to these documents, the process was explained using examples from the 2018 self-inspection, where an observation was tracked from response to corrective action, and finally through to CAPA.

Canadian Blood Services believes that the information provided and reviewed to date is sufficient to verify compliance. If there are any specific elements of the program that could not be provided, Canadian Blood Services is certainly open to discussing this matter.

Canadian Blood Services acknowledges that the 2021 self-inspection while still in progress, is on schedule. Once completed, the additional audit documentation, as listed above, will be forwarded to your attention no later than November 26, 2021.

2. **Pertaining to the 2018 self-inspection, there was no evidence that corrective actions, their implementations and effectiveness were reviewed by senior company management in a timely manner.**

As per SOP 08 031, Quality Audits, the quality audits group are responsible for tracking promised actions for observations until closure and ensuring they are completed in a timely manner. All Quality Audit reports, including corrective actions are reviewed and approved by senior management.

In addition to the documents provided as referenced in response to observation 1.1, an example from the 2018 self-inspection was provided to demonstrate how observations are tracked from response to corrective action, and finally through to CAPA and closure.

Health Canada Follow-up letter dated 2021-12-09:

The CAPA proposal has been reviewed and deemed unacceptable at this time. The CAPA did not address the inadequacy of information and records provided by Canadian Blood Services to verify compliance of your self-inspection program. Specifically, the inspection team was not able to verify that the observations from the 2018 self-inspection were assessed appropriately by Canadian Blood Services according to risk, implemented with appropriate and effective corrective actions and follow-ups, and were reviewed and approved by senior management.

As per Health Canada GUI-0001: *Good Manufacturing Practices Guide for Drug Products*, C.02.024(1) interpretation 9.b states that "records of your self-inspection program, evaluation and conclusions, and corrective measures implemented" are required to be kept and available for inspection. Your firm is expected to demonstrate compliance with C.02.024 and the GUI-0001 interpretation.

Canadian Blood Services Response (dated 2021-12-23):

As you are probably aware, this is an issue that has surfaced lately as a result of a few inspections. As such, we have reached out to the Health Product Inspection and Licensing Division to have further discussion on the interpretation of clause C.02.024 and to better understand the type of evidence that is missing as we believe that the information provided and reviewed to date is sufficient to demonstrate compliance. An initial meeting is in the process of being scheduled. Our objective is to find a solution to meet the need of Health Canada inspectors while maintaining the integrity of our internal quality audit process. We will provide an updated response once the discussions have concluded.

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: Betty Palma
Regional Regulatory Compliance & Enforcement Officer
Regulatory Operations and Enforcement Branch