

2022-06-23

CBS Control #: CBS6627

HPFB File #: C1892-100390

REF: H-2223-OTT

Kevin Donato
Regulatory Operations and Enforcement Branch
Biological Products Compliance Program
2301 Midland Avenue
Toronto, ON M1P 4R7

Dear Kevin Donato:

**Re: Responses to Health Canada Inspection of Licensed Activities at Ottawa Operations
from 2022-05-30 to 2022-06-03**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2022-06-13.

Section 117 - Records

1. **Records were not always accurate, complete, legible, indelible and/ or readily retrievable.**

Some production records were not always complete, for example,

- a) **The CAD Transfer & Split of Illuminated Platelets (F802002) form does not have a field to indicate the time of transfer out of CAD. It currently features a "transfer into CAD" field and a check box to "confirm platelets drained from CAD 6-16 hrs post transfer into CAD."**
- b) **An Electronic End Labeling (F8009390 record for clinic date 2021-09-15 did not include the "End of Record" statement on the form. [resolved during inspection]**
- c) **A Production Exception Record (F800912) for clinic date 2021-10-27 did not contain the initials of the reviewer as required in the "Reviewed and 7200 Entered by" section of the form. [resolved during the inspection]**

Response to 1a (responses to 1b and 1c were not required):

As stated in the observation the time of CAD Transfer & Split of Illuminated Platelets (F802002) form does not have a field to indicate the time of transfer out of Compound Absorption Device (CAD).

Canadian Blood Services is using a check mark as an alternative approach to provide evidence that the staff have verified the time to confirm that the time of transfer out of CAD meets the requirement of 6-16 hrs. We do not believe that the actual time needs to be recorded and that a change to that effect is required.



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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,

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Vice-President
Quality & Regulatory Affairs
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