



CANADIAN BLOOD SERVICES  
SOCIÉTÉ CANADIENNE DU SANG

2005-04-22  
CBS Control #3402  
Ref #AUD05-072 HC128  
HC File # C1892-100390

Mr. Jean-Marc Charron  
Operational Manager  
Health Products & Food Branch Inspectorate  
Ontario Operational Centre  
2301 Midland Avenue  
Toronto, ON M1P 4R7

Dear Mr. Charron:

**Re: Follow-up to the Health Canada Audit of Head Office**  
**28 February – 04 March 2005**

The following is further to Health Canada's letter of 8 April 2005 requesting the additional information on the Health Canada's audit of Head Office.

**Observation #1**

**In the event that deleted packing slips could not be re-created, there was no evidence to indicate traceability of the product to final disposition.**

*CBS Response dated 07 April 2005*

*Work instructions in SOP 05 722, Modification/Deletion of Packing Slips - MAK PROGESA and SOP 05 060, Issuing Blood and Components are being revised to include permanent retention of all packing slips and documentation handling. Therefore, traceability will be ensured in the event that an "electronic" packing slip is deleted. These measures will be implemented once the revised SOPs are approved by BGTD. These paper-based measures will be maintained until a solution to ensure traceability has been developed in PROGESA.*

**Health Canada follow up letter dated 08 April 2005**

**The CBS response indicated that the measures of permanent retention of all packing slips and documentation handling will be implemented once the revised SOP's are approved. Please indicate the interim measures that will be taken until the SOP's have been reviewed and implemented.**

*CBS Response*

*CBS would like to clarify, as was mentioned during the inspection, that it is possible to reconstruct packing slips in PROGESA. Thus, we consider no additional action necessary until the SOP revisions indicated in our initial response can be implemented.*

*The process is, however, cumbersome, therefore our proposal is to retain paper copies of the packing slips. SOP 05 722, Modification/Deletion of Packing Slips - MAK PROGESA is being reviewed for the proposed changes for future submission to Health Canada. SOP 05 060, Issuing Blood and Components, has been revised as indicated. However, this procedure is also associated with the Buffy Coat submission currently under review by BGTD. According to BGTD's Management of Blood Establishment Submissions guidelines, the version revised in*

*response to this observation should not be submitted until the version currently with BGTD is approved. BGTD has, however, agreed to make an exception in this instance and SOP 05 060 will be submitted with SOP 05 722.*

If you require any clarification, please do not hesitate to contact the undersigned. Please refer to the above control number in any correspondence.

Sincerely,



Dr. Christian Choquet  
Vice President, Quality Assurance  
and Regulatory Affairs