

2005-04-07
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: Responses to the Health Canada Audit of Head Office
28 February – 04 March 2005

The following are the actions undertaken by Head Office in response to the observations contained in the Health Canada Exit Notice.

Manufacturing control / Contrôle de la fabrication – C.02.011

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.**

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.

Personnel / Personnel – C.02.006

2. **The following were observed with respect to training:**
 - a) **there was no implemented national training programme to address the requirements for personnel involved in blood and blood component manufacturing; and**
 - b) **there was no standardized process for the development of training materials.**

We are currently assessing timelines and resource requirements in order to develop and implement a national training program, which would include the standardization of the development of training materials. We expect this assessment to be completed by June 2005 at which time we will share our proposed plan with the Inspectorate.

Manufacturing control / Contrôle de la fabrication – C.02.011

3. **During the review of the Forms/Labels Release Request (FLRR) forms, it was observed that for a shipment of Record of Donations received by the warehouse on August 5, 2004 (P.O. Number 238196), the verification of release from quarantine was not completed, contrary to Step 6 of Operating Procedure WRS 03, Version 2.0 (Effective Date: 2004-04-05). QIR # WARE0504 was generated during the inspection.**

Resolved during inspection.

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