Proliant BIOLOGICALS
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CHANGE NOTIFICATION

Date: December 1, 2021

From: Henry Turlington, Vice President, Quality Assurance & Regulatory Affairs

Subject: New Raw Material Suppliers for Bovine Liquid Plasma

Dear Valued Customer:

In our ongoing effort toward continuous quality improvement, Proliant Biologicals is pleased to announce the following process improvement.

To support a growing global market and ensure a consistent supply of key raw materials, Proliant Biologicals has approved additional raw material suppliers for liquid plasma to manufacture the following SKU's at the Boone, IA production facility. The new suppliers have been rigorously tested and validated to ensure no differences in finished products. A summary of the validation is available upon request.

The following SKU's will utilize our existing and new raw material suppliers:

- 68000 BSA Liquid Standard Grade pH 7.0
- 68100 BSA Standard Grade pH 7.0 Lyophilized Powder
- 68600 BSA Liquid Reagent Grade Fatty Acid Free
- 68700 BSA Reagent Grade, Fatty Acid Free Lyophilized Powder

US (USDA) and EU (European Commission) regulations require only ante-mortem inspection for treated blood products, such as BSA. Historically, Proliant Biologicals exclusively used edible grade plasma, which allowed the company to produce a human nutritional supplement along with Bovine Serum Albumin (BSA). Edible grade plasma has passed both ante- and postmortem inspections. Proliant Biologicals is adding suppliers to ensure the supply of BSA for its customers. The new suppliers for liquid plasma meet the regulatory requirements of ante-mortem inspection to produce BSA and satisfy export/import requirements. Product quality and processes for BSA remain unchanged.

The certificate of origin (COO) for the identified BSA finished products above is being updated to support the additional raw material suppliers, which provide liquid plasma that has passed ante-mortem inspection (see attachment below). For those unique situations where postmortem inspection may be needed by customers, new SKU's will be created for finished products where the liquid plasma passed both ante- and postmortem inspection.

This change will be effective June 1, 2022 (180 days from the notification date).

These efforts are part of our long-term commitment to quality and reliability as the world's premier BSA manufacturer. Proliant Biologicals, LLC manufacturing is completely integrated, controlling the entire process from plasma collection through drying and packaging resulting in unprecedented and unmatched control over the quality and consistency of our BSA finished products.

Please direct any questions to your Proliant Biologicals sales representative or Customer Service.

Sincerely,

Henry Turlington, Ph.D.
Vice President, Quality Assurance & Regulatory Affairs

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Certificate of Origin

This is to certify that the raw material used to manufacture Proliant Biologicals' Bovine Serum Albumin (BSA) was derived exclusively from bovine plasma at USDA-regulated abattoirs located in the USA. The animals passed ante-mortem inspection under a veterinarian's supervision and were considered free of infectious or contagious diseases and injurious parasites.

The product is manufactured exclusively from tissues which are known to be those that DO NOT harbor the agent which causes BSE. The product is manufactured in compliance with USDA regulations that prohibit the use of Specified Risk Materials (SRM) which are the tissues that harbor the infective agent. The material does not contain, nor is derived from SRM as defined in REGULATION (EC) 999/2001. The BSA was not commingled with any other material of animal origin.