



January 23rd, 2024

Dear Colleagues/Customers,

Takeda Canada was made aware of a drug shortage situation impacting GAMMAGARD[®] S/D (5 mg/vial DIN 02231470, 10 mg/vial DIN02231471) due to unexpected interruption of the manufacturing of the Baxter diluent, currently packaged with GAMMAGARD[®] S/D product.

To maintain product access for impacted patients, Takeda Canada has been authorized to distribute a limited amount of Canadian-labelled GAMMAGARD[®] S/D product packaged with sterile water for injection (sWFI) manufactured by a different supplier, in advance of the related regulatory approval. The addition of Siegfried Hameln as a new supplier of sWFI for GAMMAGARD[®] S/D is currently under review by Health Canada.

The initial supply of GAMMAGARD[®] S/D packaged with sWFI from Siegfried Hameln has the lot number BE08D019AD, and expiry of 2025-08-27.

Siegfried Hameln is supplying two sWFI fill sizes (96 mL and 192 mL) that are co-packaged with GAMMAGARD[®] S/D. The appendix provides a comparison between images of Baxter and Hameln sWFI 96mL vial and carton labels. The same differences apply to the vial and carton labels of the 192 mL sWFI fill size (images not included in appendix).

GAMMAGARD[®] S/D packaged with Hameln sWFI should be used in the same manner as product packaged with Baxter sWFI. To ensure safe use of the GAMMAGARD[®] S/D product, please refer to the GAMMAGARD[®] S/D Product Monograph for labelling information, available in English and French at <https://www.takeda.com/en-ca/ggsdpm> and <https://www.takeda.com/fr-ca/ggsdmp>. If additional information is required please contact Medical Information at 1.800.268.2772 or medinfoCA@takeda.com.

In case of any adverse event suspected, the details and the Medical Information contact details can be found online at <https://www.takeda.com/en-ca/what-we-do/our/medicines/shire-products/>. Suspected side effects can also be directly reported by email to AE.CAN@takeda.com.

To report adverse event or side effects to Health Canada, please complete the form online via <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> or by calling toll-free at 1-866-234-2345.

Sincerely,

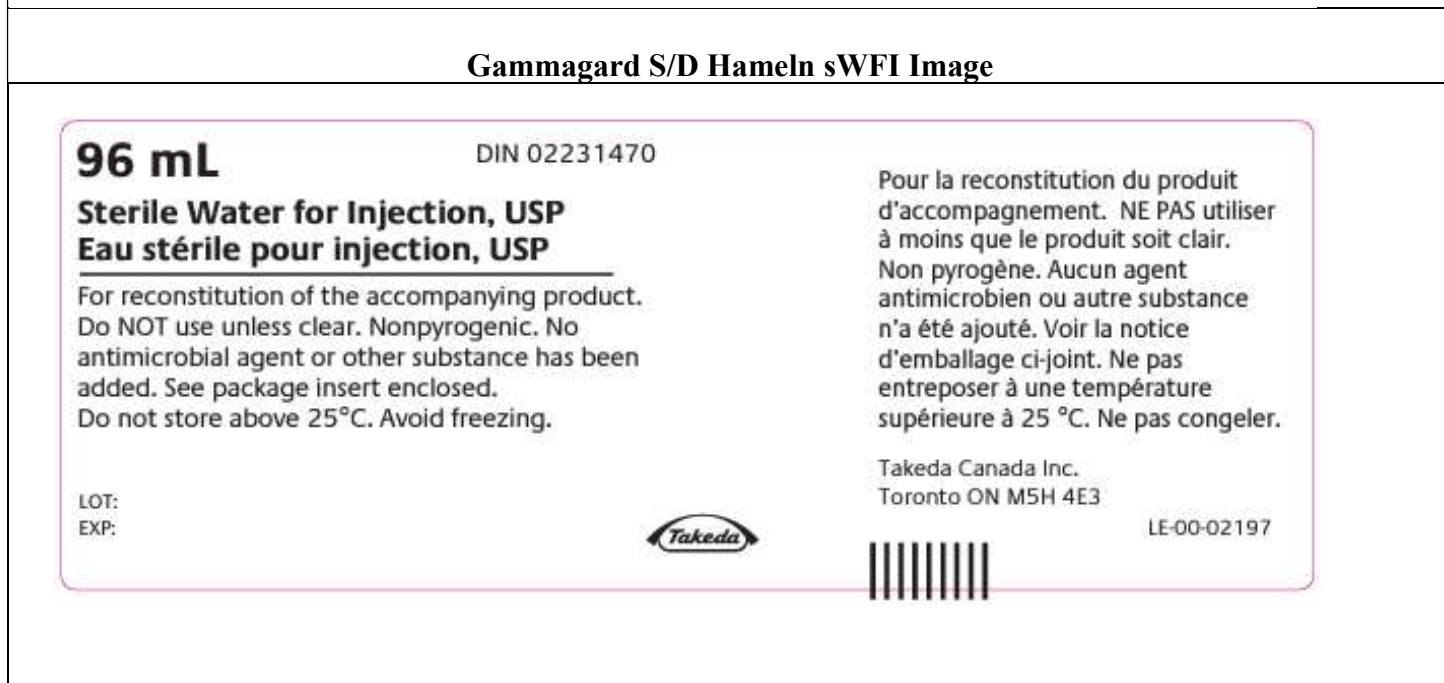
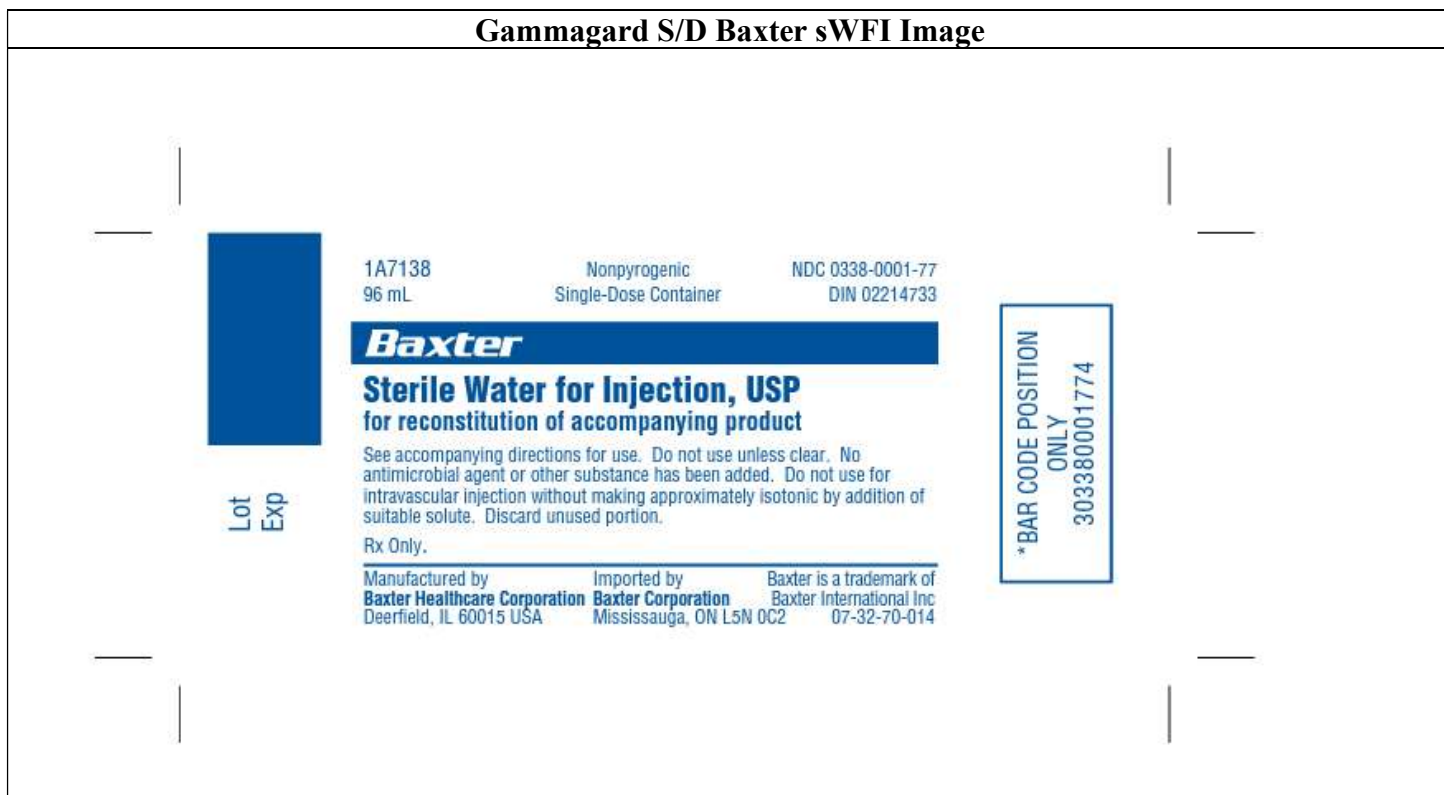
A handwritten signature in black ink, appearing to read "Jefferson Tea".

Jefferson Tea, PhD, MBA
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APPENDIX

Baxter and Hameln sWFI 96ml vial labels images

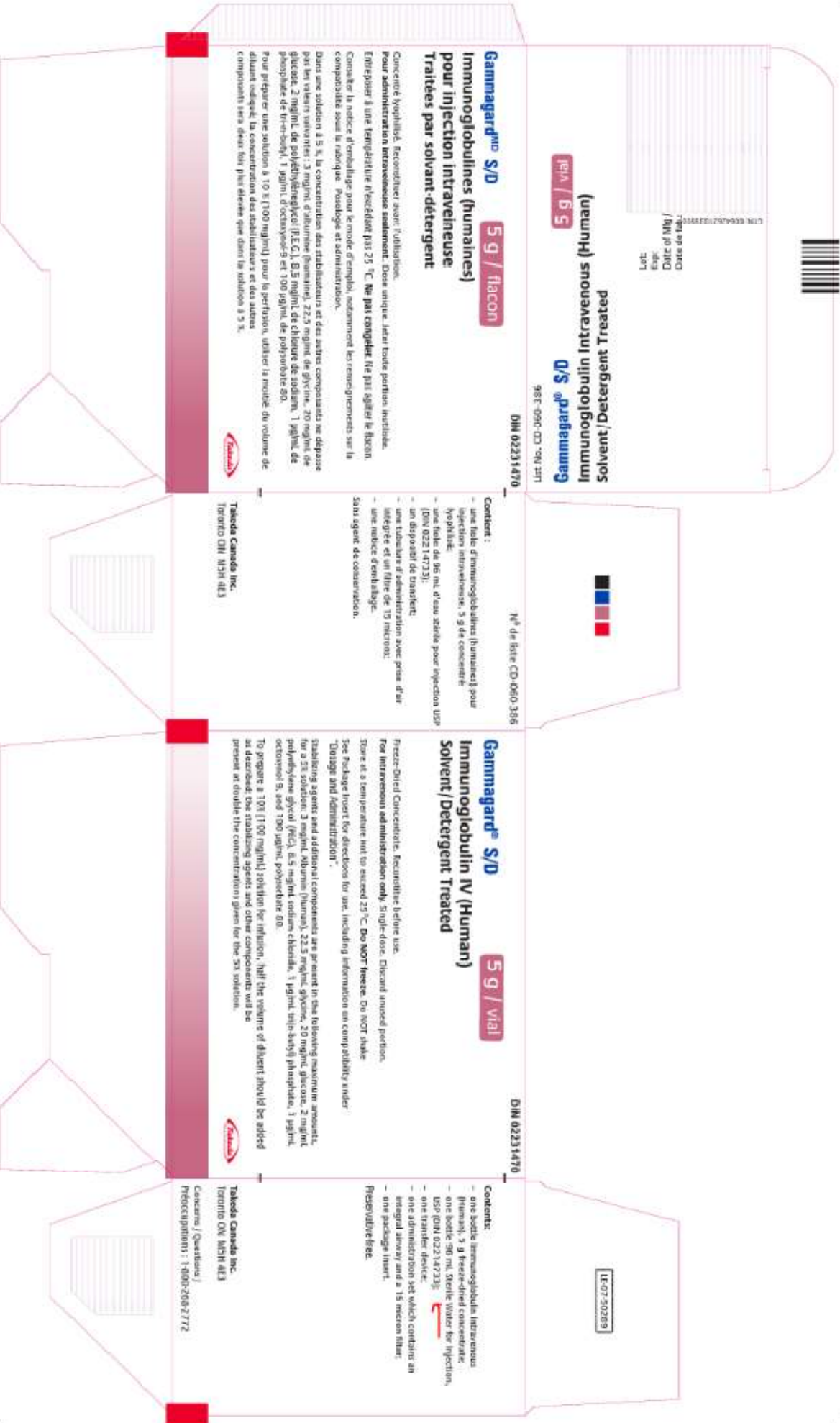
Please note, the difference between the existing Baxter diluent label and the Hameln label used for the initial supply is the storage conditions that are included on the Hameln label.



Baxter and Hameln sWFI 96ml vial Carton labels images

Please note, only difference between the carton labels is the Baxter sWFI DIN has been removed on the product cartons co-packaged with Hameln sWFI.

Gammagard S/D Carton Labels
Co-packaged with Baxter sWFI



Gammagard S/D Carton Labels
Co-packaged with Hameln sWFI

